UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION This document relates to: *"Track One Cases"*	MDL No. 2804 Case No. 17-md-2804 Hon. Dan Aaron Polster

MANUFACTURER DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY ADJUDICATION THAT DEFENDANTS DID NOT COMPLY WITH THEIR DUTIES UNDER THE FEDERAL CONTROLLED SUBSTANCES ACT TO REPORT SUSPICIOUS OPIOID ORDERS AND NOT SHIP THEM

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INTRODUCTION

After more than a year of discovery, Plaintiffs do not even attempt to identify a single order filled by a Manufacturer Defendant that they say should not have been shipped. Instead, they seek to hold Manufacturer Defendants[1] ("Manufacturers") liable for shipments of controlled substances sent by DEA-registered *distributors* to DEA-registered *pharmacies* and for diversion that allegedly occurred after the pharmacies received those shipments. In their Motion for Partial Summary Adjudication That Defendants Did Not Comply With Their Duties Under The Federal Controlled Substances Act To Report Suspicious Opioid Orders And Not Ship Them, (the "Motion"), Plaintiffs ask this Court to hold that the Controlled Substances Act ("CSA") and its implementing regulations require Manufacturers registered under the CSA to police not just the orders that *they* fill and ship, but also the orders that their DEA-registrant *customers* fill and ship—and, further, that Manufacturers failed to meet that purported requirement here. Mot. (Dkt. 1924/1910). No such requirement appears in the text of the CSA, the statute's implementing regulations, or even any guidance issued by the Drug Enforcement Administration ("DEA"). In fact, both current and former DEA officials have disavowed, including under oath in this very litigation, that the CSA requires any such thing. In addition, Plaintiffs attempt to criticize manufacturer suspicious order

[1] Manufacturer Defendants joining this Opposition include: Purdue Pharma, L.P.; Purdue Pharma, Inc.; The Purdue Frederick Company, Inc.; Endo Health Solutions Inc.; Endo Pharmaceuticals Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc.; Janssen Pharmaceuticals, Inc. f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica, Inc.; Johnson & Johnson; Noramco, Inc.; Teva Pharmaceutical Industries, Ltd.; Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Allergan plc f/k/a Actavis plc; Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Allergan Sales, LLC; Allergan USA, Inc.; Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc., f/k/a Watson Pharma, Inc.; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida; Mallinckrodt plc; Mallinckrodt LLC; and SpecGx LLC.

Teva Pharmaceutical Industries Ltd., Allergan plc f/k/a Actavis plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their pending motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this Opposition as a result of the Court's deadline to file oppositions to dispositive and *Daubert* motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges.

monitoring ("SOM") programs for not meeting Plaintiff-created "requirements" despite consistent DEA guidance and testimony—including from Plaintiffs' own expert—that the design of an SOM program is left to the individual registrants and that the SOM regulation does not create any specific requirements as to how an SOM algorithm or program must operate.

Plaintiffs' Motion should be denied as to Manufacturers for those reasons alone, as well as for the reasons set forth in Defendants' Opposition to Track One Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act and in Defendants' Response to Plaintiffs' Motion for Partial Summary Adjudication on Defendants' Compliance With the Controlled Substances Act ("CSA Compliance Brief"), pp. 1-19, both filed on July 31, 2019, which are incorporated herein by reference. In Section IV below, Manufacturers also provide still further bases for denial of the Motion as to each individual Manufacturer as Plaintiffs have failed to adduce undisputed facts evidencing that any manufacturer violated the CSA.

LEGAL STANDARD

Entry of summary judgment is proper only where the moving party demonstrates "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Where, as here, "the moving party also bears the burden of persuasion at trial, the moving party's initial summary judgment burden is 'higher in that it must show that the record contains evidence satisfying the burden of persuasion and that the evidence is so powerful that no reasonable jury would be free to disbelieve it.'" *Arnett v. Myers*, 281 F.3d 552, 561 (6th Cir. 2002); *see also Calderone v. United State*s, 799 F.2d 254, 259 (6th Cir. 1986). Summary judgment is not the time for the moving party to ask the Court to resolve disputed factual questions in its favor. *See Keller v. Miri Microsystems LLC*, 781 F.3d 799, 806, 815 (6th Cir. 2015). Rather, the Court must "view the factual evidence and draw all reasonable inferences in

favor of the non-moving party." *Williams v. Mehra*, 186 F.3d 685, 689 (6th Cir. 1999); *see also Smith v. Wal-Mart Stores, Inc.*, 167 F.3d 286, 289 (6th Cir. 1999).

ARGUMENT

I. Plaintiffs Have Not Identified *Any* Orders That Manufacturers Should Not Have Shipped to Their Customers.

Although Plaintiffs ask this Court to hold that "each of the Defendants repeatedly violated the Controlled Substances Act *in their shipments to Summit and Cuyahoga Counties*," Mot. 2 (emphasis added), Plaintiffs fail to identify a single order shipped by a Manufacturer to any customer—let alone a shipment to a customer in either plaintiff county—that was suspicious and should have been withheld.[2] Not one of the four experts Plaintiffs have retained to opine on potentially suspicious orders—Craig McCann, Lacey Keller, James Rafalski, or Seth Whitelaw—identifies a single suspicious order shipped by a Manufacturer Defendant (or one that supposedly should have been reported to the DEA). *See* Mfrs. Causation Brief at 12 (Dkt. 1894-1/1941-1). Plaintiffs' experts admitted to this fact in their depositions. *See* Rafalski Tr. 635:2-13 (Dkt. 1969-19/1983-16) ("Q. Okay. And are you offering any opinion in this litigation that any particular order shipped by a manufacturer into Summit or Cuyahoga County was suspicious? A. I'm sorry, shipped by a manufacturer -- Q. Correct. A. -- to a distributor? Q. That's right. To -- to someone in Cuyahoga or Summit County. A. No, sir."); Keller Tr. 51:6-52:15, 111:12-112:13 (Dkt. 1963-13/1979-6); McCann Tr. 415:14-18 (Dkt. 1966-17/1981-12); *see also* Whitelaw Tr. 291:3-292:4 (Dkt. 1972-7/1985-19). [3]

[2] Davison Decl. Ex. 1 Summit County's Suppl. Resp. to Manufacturer Defendants' Interrog. No. 27; Davison Decl. Ex. 2 Cuyahoga County's Suppl. Resp. to Manufacturer Defendants' Interrog. No. 28.

[3] On first reference, citations to expert reports and deposition transcripts that have been filed on the docket include the docket numbers (both sealed and public versions, respectively). Appendix A is a cross-reference chart of all such expert reports and transcripts.

Though Plaintiffs' putative experts apply "several different models" that Plaintiffs claim "would have identified thousands of suspicious orders in the relevant time period," Mot. 19, Plaintiffs have not applied any of those models to orders actually shipped by manufacturers to their customers (*i.e.*, to *distributors*).[4] Instead, these models are based solely on shipments from distributors to pharmacies, or prescriptions written by physicians to patients and purportedly attributed to manufacturers based solely on undifferentiated shipments to a distributor.[5]

Keller also attempts to tie certain orders shipped by distributors to pharmacies back to the purchases made by distributors from a manufacturer, Keller Rpt. 83-84, but as discussed in the report of defense expert Edward Buthusiem, such tracing is not possible. This is because a distributor's inventory at any one time is comprised of product purchased in many different orders placed with the manufacturer over time that are not separated out by lot number. It is, therefore, impossible to determine to which specific distributor-to-manufacturer order a downstream sale even relates.[6] Moreover, merely because a downstream sale may later turn out to be improper, or diversion later occurs downstream does not mean that there was anything suspicious about the manufacturer sale to the distributor. In other words, the bare fact that downstream diversion occurred does not suffice to show that any order was suspicious or any manufacturer's conduct was improper under the CSA.

In short, Plaintiffs have not identified a single order shipped by a single manufacturer defendant to any customer that was suspicious within the meaning of the CSA and that (even under

[4] Rafalski Rpt. 40-46 (Dkt. 2000-22/1999-21); Whitelaw Rpt. 3-4 (Dkt. 2000-26/1999-25); Keller Rpt. 10-12 (Dkt. 2000-7/1999-7); McCann Rpt. 26-33 (Dkt. 2000-14/1999-13); McCann 2d Supp. Rpt. 2-3 (Dkt. 2000-16/1999-15).
[5] McCann Rpt. 29-30; McCann 2d Supp. Rpt. 3-9; Keller Rpt. 10-12.
[6] Buthusiem Rpt. 5 (Dkt. 1939-5/1936-5).

Plaintiffs' theory of the CSA) should have been reported to the DEA and purportedly halted.[7] This alone requires the Court to deny the Motion.

II. Plaintiffs' Attempt to Invent a New Manufacturer Legal Obligation to Monitor Orders After They Are Shipped To Distributors Is Fatally Flawed.

Unable to identify a single suspicious order that should not have been shipped by a manufacturer, Plaintiffs resort to inventing a duty that does not exist. They claim that, under the CSA, manufacturers are required not only to monitor and report suspicious orders that they are asked to fill by their own distributor customers, but also to monitor and report any suspicious activity in those distributors' sales and shipments to pharmacies.[8] Such an obligation appears nowhere in the CSA, its implementing regulations, or any industry guidance provided by the DEA. Indeed, time and again DEA witnesses that were deposed in this case made clear that no such legal obligation exists. *See* Wright Tr. 201:24-202:1 (Dkt. 1972-12/1985-24); Ashley Tr. 159:20-161:8 (Dkt. 1956-7/1974-7); Rannazzisi Tr. 110:7-18 (Dkt. 1969-20/1983-17).

A. The Suspicious Order Monitoring Regulation does not create a legal duty for manufacturers to monitor downstream orders or know their "customers' customers."

There is no requirement for manufacturers to monitor downstream sales made by their distributor customers because the governing law does not include any such obligation. Manufacturers' suspicious order monitoring obligations are established by the CSA's implementing regulations. Although the term "suspicious order" did not exist within the CSA

[7] It bears repeating that the CSA and its implementing regulations do not impose a duty to halt orders identified as suspicious. *See* 21 U.S.C. § 801 *et seq.*; 21 C.F.R. § 1301 *et seq.* But even under Plaintiffs' theory of the CSA, they have not identified any order by a manufacturer that was suspicious and should have been stopped.

[8] In apparent recognition of the weaknesses of their legal arguments against manufacturers, Plaintiffs' assertion that manufacturers are required to police downstream activity is noticeably absent from Plaintiffs' separate motion for partial summary judgment regarding Defendants' duties under the CSA. (Dkt. 1887). Nor do Plaintiffs argue in the present Motion that manufacturers have a duty to monitor downstream sales of their products. Rather, Plaintiffs assume that such a duty exists and then proceed to seek summary adjudication that certain Manufacturers in fact violated that duty. That faulty premise destroys all of Plaintiffs' arguments for partial summary adjudication against the Manufacturer Defendants.

when enacted in 1971, DEA promulgated through notice-and-comment rulemaking in 1973 a regulation (the "Suspicious Order Monitoring Regulation") requiring:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74(b). This regulation is clear on its face: Registrants are responsible for reporting suspicious orders received from their own customers. Nowhere in the regulation is there any indication that manufacturers are required to monitor and report suspicious sales by their customers—typically, highly sophisticated wholesale distributors who have their own SOM systems—to downstream pharmacies (*i.e.*, their "customer's customer"). This plain language is dispositive.

DEA witnesses, including Demetra Ashley, the Former Acting Assistant Administrator of the DEA's Diversion Control Division, confirmed this plain reading of the statute and its implementing regulations. Ashley Tr. 159:20-161:8 ("Q. As you sit here today, are you aware of any statute that requires a manufacturer to know its customer's customer? A. No, I am not aware of a statute that says that. Q. What about a regulation? A. No, I'm not aware of a regulation that says that."). There is simply no statutory or regulatory requirement to monitor orders placed by a customer's customer.

The structure of the CSA further supports this point. The Suspicious Order Monitoring Regulation falls within the "Security Requirements" regulations promulgated by DEA, confirming that it applies to orders handled by registrants themselves, not orders placed by their customers' customers. Each of the enumerated security requirements focuses on obligations of a registrant when the product is within its custody and control. For example, registrants must maintain

physical security controls and take steps before shipping an order to ensure that a customer is registered to possess a controlled substance. 21 C.F.R. § 1301.74(a). The Security Requirements include multiple detailed obligations for a registrant with respect to its own customers, but nowhere is there a mention that a registrant is expected to know or monitor its "customers' customers" or utilize data to look at the sales by its customers downstream. *See* 21 C.F.R. §§ 1301.71-1301.77. If such a requirement existed, there can be no doubt that in the hundreds of regulations promulgated by DEA regarding the manufacturing, handling, and shipping of controlled substances, DEA would have included such a requirement.

Indeed, the Supreme Court has explained that "the CSA creates a comprehensive, closed regulatory regime." *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006); *see also id.* at 274 ("[T]he conventions of expression indicate that Congress is unlikely to alter a statute's obvious scope and division of authority through muffled hints . . . . "). "The judiciary may not, in the face of such comprehensive legislative schemes, fashion new remedies that might upset carefully considered legislative programs." *Nw. Airlines, Inc. v. Transp. Workers Union of Am., AFL-CIO*, 451 U.S. 77, 97 (1981); *see also id.* ("The presumption that a remedy was deliberately omitted" is "strongest when Congress has enacted a comprehensive legislative scheme including an integrated system of procedures for enforcement."). Plaintiffs' Motion should be denied.

B. The CSA's Effective Controls Against Diversion Provision does not create a legal duty for manufacturers to monitor downstream orders or know their customers' customers.

In light of the clear language of the Suspicious Order Monitoring Regulation, Plaintiffs attempt to tie manufacturers' supposed duty to monitor their "customers' customers" to language in the CSA regarding DEA's obligation to consider whether a manufacturer maintains effective controls against diversion when determining whether to grant a registration. *See* Mot. 4. In order to manufacture a Schedule I or Schedule II controlled substance, manufacturers are required to

apply for a registration with the DEA and to renew that registration annually. 21 U.S.C. § 823(a)(1); 21 C.F.R. § 1301.13(e)(i). Before granting or renewing a manufacturer's registration, the DEA must consider, *inter alia*, whether the manufacturer "has provided effective controls against diversion." 21 U.S.C. § 823(a)(1).

What constitutes "effective controls against diversion" is clearly explained by an enumerated list of factors the DEA must consider. These factors are limited to "the security requirements set forth in Secs. 1301.72-1301.76 as standards for physical security controls and operating procedures necessary to prevent diversion."[9] 21 C.F.R. § 1301.71. Nowhere in the "Security Requirements" is there a reference to monitoring the sales of a manufacturers' customers or the prescribing habits of physicians. Instead, those "Security Requirements" relate to the manner in which registrants must store, secure, and ship controlled substances in order to guard against diversion due to theft. *See* 21 C.F.R. §§ 1301.72-1301.76. In other words, the regulations impose obligations during the period when the registrant has possession of a controlled substance and can be expected to guard against diversion—*e.g.*, securing against the theft of controlled substances in its possession or monitoring orders placed with the registrant. *Id.* There is simply no support in the regulations for Plaintiffs' position that in order to "maintain effective controls against diversion," a registrant is required to monitor and report the downstream sales and shipments of its customers (which are themselves DEA registrants with security and reporting obligations of their own) to other third-party DEA registrants or the prescriptions written by duly

[9] The term "operating procedures necessary to prevent diversion" does not require manufacturers to review sales by their customers. Any such interpretation would make the requirement that the DEA look to the Security Requirements when evaluating effective controls against diversion superfluous. It is a basic principle of regulatory interpretation that words and phrases must be read in context within the regulatory regime and that general statements cannot be read to override specific enumerated items. *Yates v. United States*, 135 S. Ct. 1074, 1086-87 (2015).

licensed physicians for patients.[10] *See generally Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346, 1355 (S.D. Fla. 2003) (finding that CSA does not impose duty on manufacturers to report doctors to law enforcement or licensing authorities).

C. DEA guidance letters and sworn testimony confirm that there is no regulatory obligation for manufacturers to monitor the sales of their customers.

In the more than 40 years since the Suspicious Order Monitoring Regulation was promulgated, DEA has never once issued a notice to manufacturers informing them that they must monitor orders their distributor customers receive from their (distributors') own pharmacy customers. In 2006 and 2007, DEA sent "Dear Registrant" letters to registrants within the controlled substances supply chain purporting to "reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b)." Pls. Ex. 4 2006 Rannazzisi Letter (Dkt. 1957-4); Pls. Ex. 6 2007 Rannazzisi Letter (Dkt. 1957-6). Neither letter contains any assertion that manufacturers have a duty to monitor and report sales that their customers then later make to pharmacies or to know their "customers' customers." Instead, the letters (which themselves are not interpretative rules) focus exclusively on DEA's expectations regarding the monitoring and reporting of orders received *directly by the registrant*. DEA has not provided, and Plaintiffs do not cite, any agency guidance that creates an obligation for manufacturers to know their customers' customers.[11]

[10] Plaintiffs' view of the standards that manufacturers must meet in order to "maintain effective controls against diversion" would create liability for manufacturers for seemingly endless acts. The Sixth Circuit has rejected such overbroad readings of statutory obligations. *See, e.g., Crosby v. Twitter, Inc.*, 921 F.3d 617, 625 (6th Cir. 2019).

[11] To the extent that certain industry conferences put on by private companies discussed monitoring orders or individual DEA agents made one-off comments to registrants that such an expectation may exist, such information is insufficient to create a duty that is outside the scope of the requirements of the CSA and its implementing regulations. *See S. Forest Watch, Inc. v. Jewell*, 817 F.3d 965, 972 (6th Cir. 2016) (explaining that "nonlegislative 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice' . . . lack the force and effect of law" (quoting 5 U.S.C. § 553(b)–(c)); *cf. Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) ("[W]e [have] held that interpretive rules . . . do *not* have the force of law.").

The DEA witnesses consistently testified that there is no requirement under the CSA or its implementing regulations for manufacturers to monitor downstream orders or know their customers' customers. DEA's 30(b)(6) witness—designated by DEA to testify for the agency regarding, among other things, DEA's interpretation of the Suspicious Order Monitoring Regulation and DEA's guidance to Defendants regarding the same—confirmed that DEA has never issued any industry-wide guidance requiring manufacturers to review chargeback data, prescription data, or any other downstream order data as part of their suspicious order monitoring obligations. Prevoznik Tr. Vol. 1 325:8-326:5, 346:24-347:5; Prevoznik Tr. Vol. 3 1200:11-23 (Dkt. 1969-14/1983-11). Similarly, Ms. Ashley testified that there is no statutory or regulatory requirement for manufacturers to know their customers' customers. Ashley Tr. 159:20-161:8. Joseph Rannazzisi, who served as the head of the Office of Diversion Control until the end of 2015 testified that he had never head the phrase "know your customers' customers" while he was at DEA. Rannazzisi Tr. 110:7-18.

There is simply no support in the statute, regulations, or even any DEA guidance or testimony for Plaintiffs' position that Manufacturers' suspicious order monitoring programs were somehow deficient as a matter of law in failing to report orders shipped by distributors to pharmacies in the Track One jurisdictions. As a result, Plaintiffs' motion must be denied.

D. Manufacturers' obligations under the CSA do not rise and fall based on what data is available to them.

Plaintiffs suggest that because manufacturers may have had available to them certain data reflecting some transactions further down the chain of commerce, the CSA somehow requires manufacturers to use that data to monitor downstream transactions of their customers' customers.[12]

[12] Plaintiffs allege that *some* manufacturers had access to *some* downstream data, including chargeback data, 867 and 852 data, and Xponent data. Mot. at 14-17. Chargeback data refers to information a distributor provides to a manufacturer when submitting a chargeback request. *See, e.g.* Buthusiem Rep. 3–4. A "chargeback" is a financial

Mot. 14-17. Plaintiffs have it backwards. Legal obligations arise from statutes and their implementing regulations. *See Madison-Hughes v. Shalala*, 80 F.3d 1121, 1125 (6th Cir. 1996). They are not created because certain data happens to be "available" to a particular registrant at any given time. *See, e.g.*, *Eaton v. Cont'l Gen. Ins. Co.*, 147 F. Supp. 2d 829, 833–34 (N.D. Ohio 2001) (no obligation for insurance company to notify patients of positive test results, even when insurance required the testing and had access to the results); *Reed v. Knox Cty. Dep't of Human Servs.*, 968 F. Supp. 1212, 1220 (S.D. Ohio 1997) (state agency under no obligation to provide information about children placed in foster homes, even assuming the agency had the information). Indeed, had Congress or the DEA mandated that manufacturers consider certain data regarding downstream transactions when monitoring for suspicious orders, they would have said so. *Terry v. Tyson Farms, Inc.*, 604 F.3d 272, 283 (6th Cir. 2010) (applying *expressio unius est exclusion alterius* rule of statutory construction that inclusion of some activities in statutory language implies the exclusion of others).

Plaintiffs' "expert" testimony—the *only* source of any supposed obligation to monitor downstream transactions—illustrates the flaw in Plaintiffs' logic. With respect to IQVIA Xponent data, which is post-shipment data regarding prescriptions written by physicians (not orders), James Rafalski testified that the CSA and its implementing regulations do not require Manufacturers to purchase IQVIA Xponenet data and that DEA could not take action against a Manufacturer based on the Manufacturer's failure to purchase that data. Rafalski Tr. 645:7-646:16. According to Mr. Rafalski, however, *if* a Manufacturer has that data in its possession, the Manufacturer *must* use it

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reconciliation mechanism whereby, under the terms of a contract between a manufacturer and distributor, the distributor submits a request to the manufacturer for a chargeback when the distributor has sold the manufacturer's product for less than what the distributor paid for it. *Id.* 867 and 852 data reflects information related to distributors' inventory levels and downstream sales that may be provided to manufacturers pursuant to contractual agreements between individual manufacturers and distributors. Xponent data provides information regarding physicians' prescribing practices and is collected and made available for sale by a third-party, IQVIA; certain manufacturers may use this data to assist them in identifying physicians to whom they may wish to market certain branded products.

as part of its suspicious order monitoring program in order to "maint[ain] effective controls against diversion" under the CSA. Rafalski Tr. 646:17-647:25.

This makes no sense. Under Plaintiffs' interpretation of the CSA, manufacturers' obligations would be determined not by the text of the statute or the implementing regulations, but rather by the business decisions that a manufacturer makes with respect to purchasing data. Such an interpretation has no basis in the law and has been expressly contradicted by DEA witnesses in this litigation. Manufacturers' mere possession of data does not entitle Plaintiffs to a summary judgment ruling that *the CSA or its implementing regulations* requires manufacturers to police transactions between other DEA-regulated and registered downstream parties.[13]

III. The Suspicious Order Monitoring Regulation Does Not Create Specific Requirements as to How a Manufacturer's Program Must Be Run.

In addition to attempting to create legal duties for manufacturers that do not exist, Plaintiffs' motion for partial summary adjudication fails for an additional reason: Plaintiffs' attempt to dictate universal "requirements" for an effective SOM program is directly contrary to the Suspicious Order Monitoring Regulation, which expressly permits each registrant to design its own unique SOM program. *See* CSA Compliance Brief, Background. As the testimony of the DEA's Rule 30(b)(6) designee on this topic succinctly explains, "the DEA leaves it up to each registrant to design a system that works with its own business model and customer base." Prevoznik Tr. Vol. 1 180:7-11. Indeed, Plaintiffs' own expert admits the same.[14] The question of

[13] Plaintiffs also ignore the many limitations in that data—which do not and cannot even provide a full or accurate picture of orders placed by manufacturers' customers' customers. *See e.g.*, Nicholson Rpt. at ¶¶ 230-238 (Dkt. 1939-27/1936-27).

[14] *See* Rafalski Rpt. 12-13 ("Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ('SOMS'), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; ***it is free to design its SOMS using any algorithms and rules it believes will get the job done***." (emphasis added)).

whether a registrant's Security Requirements, which include the SOM program, are in "substantial compliance" with the CSA, *see* 21 C.F.R. § 1301.71(b), is thus a fact-intensive inquiry that requires consideration of the particulars of the registrant's business model and customers. Plaintiffs' broad brush attempt to paint individual manufacturers as having violated the CSA because, for example, a manufacturer's SOM program allegedly relies too heavily on the use of a threshold formula or on information received from sales representatives must therefore be rejected.

IV. Manufacturer Defendants Complied With Their Obligations Under the CSA

For all of the above reasons, this Court should deny Plaintiffs' Motion for Partial Summary Adjudication. However, even if the Court finds that the alleged duties exist, there is a dispute of material fact as to whether each Manufacturer Defendant complied with these purported duties.

A. Mallinckrodt Complied With Its Obligations Under The CSA

In addition to hinging on the non-existent "duties" discussed above, *see supra* Section II, Plaintiffs' assertion that Mallinckrodt violated the CSA is based entirely on allegations that are plainly disputed and, in many cases, downright false.

First, Plaintiffs' premise that Mallinckrodt shipped orders that it should not have shipped is wholly unsupported. Plaintiffs have not identified a single order that Mallinckrodt shipped that resulted in diversion; in fact, Plaintiffs identify no order Mallinckrodt shipped to the Bellwether counties at all. In other words, Plaintiffs fail to do with the benefit of hindsight what they say Mallinckrodt somehow should have done years ago: identify which orders would be diverted and stop them. Second, each of Plaintiffs' assertions about how Mallinckrodt allegedly failed to comply with its obligations (both actual CSA obligations and those purported obligations invented by Plaintiffs) relies entirely on disputed or misstated "facts." Accordingly, this Court must deny Plaintiffs' motion for partial summary judgment as to Mallinckrodt.

1. Plaintiffs Fail To Identify Any Orders Shipped By Mallinckrodt.

Plaintiffs' bedrock assertion—"that each of the Defendants repeatedly violated the Controlled Substances Act *in their shipments to Summit and Cuyahoga Counties*," Mot. at 2 (emphasis added)—plainly does not apply to Mallinckrodt. Other than a single order shipped to Cleveland Clinic in 1998 (which Plaintiffs do not allege was suspicious), there is no evidence that Mallinckrodt shipped *any* opioid products to either Bellwether county at *any* time. Davison Decl. Ex. 3 Bellwether Counties Direct Sales Data (MNK-T1_0001820275). That should end the matter.

But Plaintiffs attempt a sleight-of-hand: gliding, hopefully unnoticed, from their initial (unsupported) assertion that Mallinckrodt *shipped* suspicious orders, to the entirely different position that Mallinckrodt "fail[ed] to detect that significant amounts of its opioid products *were being shipped* [*by its customers*] under circumstances indicative of diversion." Mot. at 27.[15] (emphasis added). First, even assuming that any orders shipped by Mallinckrodt's customers were suspicious (which is obviously a question of disputed fact), Mallinckrodt was not obligated to police these orders. *See supra* Section II. There is no statutory or regulatory obligation under the CSA that Mallinckrodt assess every order down the supply chain for whether it is "being shipped under circumstances indicative of diversion." Mot. at 27. Second, contrary to Plaintiffs' suggestion, chargeback data would not enable Mallinckrodt to link any downstream order sent to the Bellwether counties to a specific direct sale Mallinckrodt made to a distributor. Buthusiem Rpt. 6 (Dkt. 1939-5/1936-5) (explaining that in Mallinckrodt's chargeback data "there is (a) no information submitted by the distributor on the chargeback request indicating the direct manufacturer-to-distributor sale(s) from which the chargeback inventory was sourced, and (b) no

[15] Similarly, Plaintiffs cite the report supplement of Craig McCann to assert "Attributing ***suspicious orders shipped by distributors*** to Summit and Cuyahoga Counties to the manufacturers who made the drug, between 26.2% and 92% of the Mallinckrodt MMEs shipped in Summit and Cuyahoga Counties were part of suspicious orders, depending on the SOM metric applied." Mot. at 26 (emphasis added). Again, Dr. McCann identifies only purportedly suspicious orders of Mallinckrodt's *customers*. He does not say that any Mallinckrodt shipment was suspicious. Davison Decl. Ex. 4 McCann Tr. 634:20-635:8.

way to accurately link, or trace, a chargeback to a direct sale"). Accordingly, even if Mallinckrodt were obligated to monitor specific sales of its customers' customers (which it is not), there is at the very least a question of material fact as to how any allegedly suspicious downstream order could be linked to conduct—*e.g.*, a particular shipment—by Mallinckrodt.

2. Mallinckrodt Has At All Times Complied with its Suspicious Order Monitoring Obligations.

Plaintiffs' argument that Mallinckrodt failed to comply with its CSA duties (both real and invented) with respect to suspicious orders relies on facts very much in dispute. As they point to alleged deficiencies in the company's suspicious order monitoring program, Plaintiffs cherry-pick and distort some evidence, while ignoring other evidence that contradicts their assertions. Labeling facts "undisputed" does not make them so. A complete reading of the record reveals that not only are Plaintiffs' claims in dispute—they are wrong.

(a) Mallinckrodt's use of algorithms in its SOM program complied with the CSA and DEA regulations.

As an initial matter, Plaintiffs' assertion that Mallinckrodt's suspicious order monitoring program was "primarily based on a threshold formula" (Mot. at 28) is a red herring. Neither the CSA nor the implementing regulations prohibit registrants from basing their suspicious order monitoring programs "primarily" on a "threshold formula."

In any event, Plaintiffs' argument is factually incorrect. Mallinckrodt's SOM program has always included ***both an algorithm and non-algorithmic components***. Plaintiffs' unsupported assertions that Mallinckrodt relied primarily on "rigid formulas" and that "if an order did not exceed the threshold set by Mallinckrodt's numeric formula, it was not flagged as 'peculiar' and therefore not examined at all," Mot. at 29-30, are flatly contradicted by ample record evidence. In fact, Mallinckrodt has utilized a comprehensive range of additional tools, procedures, and systems to flag potentially suspicious orders, including, but not limited to, the following:

- Screening all new customers, a process that included a review of new customers' DEA licenses,[16] a Dun and Bradstreet credit report check,[17] a new customer checklist,[18] and later, a pharmacy information sheet;[19]
- Monitoring all incoming orders and escalating anything that looked potentially suspicious;[20]
- Regularly meeting with customers and raising any red flags indicative of diversion;[21]
- Reviewing every DEA 222 form to verify that every order is shipped to a valid DEA registration;[22]
- Training new hires on security and controlled substances compliance so that employees understand the consequences of non-compliance with the regulations;[23]
- Training the sales force annually on the suspicious order monitoring procedures to instruct the sales team on the DEA regulations, an update on Mallinckrodt's SOM program, and the sales team's role in SOM;[24]
- Conducting audits of its distributor customers,[25] as well as audits of downstream pharmacies;[26] and
- Conducting media searches and monitoring the Federal Register for new information about DEA registrants.[27]

Simply put, Plaintiffs' contention that Mallinckrodt primarily relied on a rigid formula is contradicted by the record.

(b) Mallinckrodt's SOM program detected and reported suspicious orders.

Plaintiffs next claim that Mallinckrodt's SOM system failed to identify and report suspicious orders. This is incorrect. Plaintiffs first state (incredibly, without citing any support)

[16] Davison Decl. Ex. 5 2009 Policy for New Customer Account Set-up and Existing Customer Account Ongoing Review (MNK-T1_0000264265).
[17] Harper Tr. 282:4-8 (Dkt. 1962-19/1977-24); Rausch Tr. 128:21-129:1 (Dkt. 1970-3/1983-21).
[18] Harper Tr. 160:22-161:5, 281:17-282:5.
[19] Harper Tr. 167:4-18.
[20] Harper Tr. 59:1-61:24.
[21] Harper Tr. 59:1-61:24; Spaulding Tr. 108:3-22 (Dkt. 1971-1/1984-19); Gillies Tr. 90:5-14 (Dkt. 1962-10/1977-15); Davison Decl. Ex. 6 Stewart Tr. 148:22-149:17; Rausch Tr. 46:20-47:10.
[22] Harper Tr. 59:1-61:24; Rausch Tr. 57:5-21, 61:8-22, 65:6-16; Stewart Tr. 48:11-49:15, 148:22-149:17.
[23] Spaulding Tr. 140:13-144:2.
[24] Davison Decl. Ex. 7 (MNK-T1_0002250046); Rausch Tr. 130:12-25.
[25] Harper Tr. 391:11-20.
[26] Ratliff Tr. 59:10-21 (Dkt. 1970-1/1983-19); Davison Decl. Ex. 8 (MNK-T1_0008561129); Davison Decl. Ex. 9 (MNK-T1_0008500998).
[27] Harper Tr. 473:23-474:14, 476:6-17, 482:24-483:11.

that between 2003 and 2011, Mallinckrodt shipped 53 million orders of opioid products and halted and reported only 33 of those orders. Mot. at 30. Between 2003 and 2011, Mallinckrodt shipped fewer than 1 million orders of opioid products (and, as discussed above, *none to the Bellwether counties*). Davison Decl. Ex. 10 National Direct Sales Data (slipsheet referencing MNK-T1_0007897646, which Mallinckrodt will submit in native format). Plaintiffs provide no support for their conclusory claim that Mallinckrodt halted and reported only 33 orders. And regardless of the number of orders Mallinckrodt shipped or reported, that is not a basis for Plaintiffs' request for adjudication, as a matter of law, that Mallinckrodt failed to comply with its legal obligations. There is no requirement under the CSA or its implementing regulations to report a set percentage of orders.

Plaintiffs' attempts to identify purported deficiencies in Mallinckrodt's suspicious order monitoring program are similarly undermined by the record. First, Plaintiffs maintain that Mallinckrodt shipped orders without completing due diligence. This is clearly contradicted by record evidence. *See* Davison Decl. Ex. 11 December 8, 2011 SOM Policy explanation (MNK-T1_0000571916) (noting that "All Unusual Orders will be subject to a password protected ship hold pending investigation); *see also* Davison Decl. Ex. 12 (MNK-T1_0007476261); Davison Decl. Ex. 13 (MNK-T1_0000511246).

Second, Plaintiffs' assertion that the evidence in this case "demonstrate[s] that from 2008 through 2009, Mallinckrodt's suspicious order monitoring program consisted *solely* of verifying DEA 222 forms," Mot. at 31, is inaccurate. As discussed above, among other things, customer service representatives, *at all times*, monitored every incoming order and flagged potentially suspicious orders. Rausch Tr. 46:20-47:10; Stewart Tr. 148:22-149:17 (customer service representatives "evaluated every order that they entered for anomalies" and flagged those that were

unusual); Harper Tr. 59:1-61:24. Indeed, ***Plaintiffs' own brief*** contradicts the assertion that Mallinckrodt's suspicious order monitoring program did nothing more than verify DEA 222 forms during 2008 and 2009; the brief cites to emails from those same years demonstrating that Mallinckrodt employees were identifying and investigating potentially suspicious orders. Mot. at 33-34. In addition, in 2009, Mallinckrodt conducted an unprecedented comprehensive audit of a distributor customer and was praised by the DEA for doing so. Davison Decl. Ex. 14 (MNK-T1_0000562325) (email from Bill Ratliff describing meeting with Pete Kleissle, DEA St. Louis Diversion Investigator, at which Kleissle informed Mallinckrodt that it "had acted in a responsible way and he saw no issues with regard to this matter").

Third, the record evidence contradicts Plaintiffs' claim that Mallinckrodt gave National Account Managers a key role in investigating and clearing orders. While National Account Managers were often called upon to provide important insight into customer history and ordering patterns, the SOM Team, not the National Account Managers, made all final decisions as to whether an order would ship. For example, Karen Harper testified that while National Account Managers were "trained . . . to be vigilant for any potential sign [or] red flags that could be indicative of diversion as they visited customers" and "assisted in the review," "***the ultimate decision about whether an order was suspicious or not rests – always did rest with the controlled substances compliance group***." Harper Tr. 59:16–19; 292:12–17. Similarly, former National Account Manager, Lisa Cardetti, former Director of National Accounts Bonnie New, former Customer Service Manager Cathy Stewart, and former Product Manager Kate Neely all testified that suspicious order monitoring had the final say as to whether or not a product shipped. Cardetti Tr. 292:21-293:3 (Dkt. 1959-17/1975-17) ("as we were trained, this information was getting to the appropriate place, in suspicious order monitoring, who was making those decisions"), Cardetti Tr.

148:16-149:6; New Tr. 106:20-107:3 (Dkt. 1968-19/1982-15); Stewart Tr. 114:23–115:15; Neely Tr. 85:15-86:10 (Dkt. 1968-17/1982-13); *see also* Davison Decl. Ex. 15 (MNK-T1_0001522039) (email from former Director of National Accounts Bonnie New stating "I would like for this order to ship but realize that the SOM Team and Jennifer B. have the final decision").

In sum, like Plaintiffs' other "undisputed facts," Plaintiffs' assertion that Mallinckrodt failed to detect and report suspicious orders is neither "undisputed" nor a "fact." It is an argument lacking actual support in the record.

(c) Record evidence contradicts Plaintiffs' assertions that Mallinckrodt "failed to use reasonably available chargeback data."

Plaintiffs' further claim that Mallinckrodt violated a regulatory obligation by failing to use chargeback data as part of its suspicious order monitoring program has at least three flaws. First, Mallinckrodt is under no obligation to use chargeback data as part of its CSA obligations. *See supra* Section II.

Second, despite having no obligation to do so, Mallinckrodt *did* use chargeback data in developing its groundbreaking and innovative efforts to prevent downstream diversion. In fact, following a self-initiated, proactive internal analysis, Mallinckrodt requested a meeting with the DEA in order to share information regarding how chargeback data could be used to examine downstream transactions and *potentially* identify circumstances indicative of diversion. Plaintiffs' expert, former DEA Diversion Investigator James Rafalski testified ***that DEA was not aware that chargeback data existed before Mallinckrodt informed DEA that it was using this data in its anti-diversion program***. Rafalski Tr. 652:5–22 (Q. So, in fact, before the meeting with Mallinckrodt that you mentioned, DEA had never publicly, certainly, told anyone that using chargeback data was part of the responsibilities of being a DEA registrant, correct? A. My experience and the information that's available to me would indicate that I'm not aware that the

DEA had any knowledge that those existed. Q. Before August 2011? A. No. I think prior to that, but related to the Mallinckrodt investigation, prior to that, I don't know that anyone was aware that that -- that chargeback – that whole chargeback relationship existed in the industry, at least from everything I've learned about that issue."). Mallinckrodt also ***invented a mechanism to deter potential diversion*** by restricting chargeback payments to its customers for sales to certain pharmacies about which Mallinckrodt had concerns. Davison Decl. Ex. 16 November 1, 2010 Mallinckrodt Letter to DEA St. Louis (MNK-T1_0000373856); Davison Decl. Ex. 17 November 1, 2010 Mallinckrodt Letter to DEA Albany Division Office (MNK-T1_0000288483). Indeed, Plaintiffs themselves cite many examples of Mallinckrodt's novel and inventive use of chargeback data. Mot. at 35.

Third, Plaintiffs' apparent preference for how manufacturers use chargeback data—to identify suspicious orders from their distributor customers—is, in fact, not possible. Mallinckrodt receives chargeback data about a bottle *after* it ships that bottle to the distributor and the distributor sells that bottle to a pharmacy; but Mallinckrodt cannot trace a pill from a downstream sale to a particular earlier direct sale. *See supra* Section IV.A.1. Plaintiffs claim that Mallinckrodt should have done the impossible: go back in time and refuse to ship a pill based on where the distributor eventually sends it. Plaintiffs' contention that Mallinckrodt should have been using chargeback data to monitor orders from its own customers not only lacks a legal basis—it reflects a fundamental misunderstanding of how chargeback data works and its limited usefulness in preventing downstream diversion.

(d) Plaintiffs' assertion that Mallinckrodt "*admitted it failed to maintain effective controls about diversion*" is plainly false.

Plaintiffs also contend that Mallinckrodt has "admitted, in an agreement with the U.S. Department of Justice and the Drug Enforcement Administration, that it failed to maintain

effective controls against diversion." That is a blatant misrepresentation. There is no such admission in any agreement with anyone. In fact, the July 2017 Administrative Memorandum of Agreement between Mallinckrodt and the DEA ("MOA") explicitly states: "This Settlement Agreement ***is not an admission of liability*** for civil penalties for the Covered Conduct under the Controlled Substances Act." Davison Decl. Ex. 18 MOA 3 (MNK-T1_0000557100). Plaintiffs disregard that language, relying instead on the DEA's ***allegations*** of wrongdoing as "evidence" that Mallinckrodt failed to maintain effective controls against diversion. *See* Mot. at 27–28. Allegations are not evidence, however, and Mallinckrodt disputed the DEA's allegations as strongly then as it does now.

In order to settle the DEA's claims, Mallinckrodt made two limited admissions: (1) **prior to 2012**, "certain aspects" of its system did not meet the standards outlined in two DEA ***guidance letters***; and (2) it did not meet certain recordkeeping and physical security requirements at its factory in upstate New York that were ***unrelated*** to suspicious order monitoring. Davison Decl. Ex. 18 MOA 3-4. As to the first, DEA's guidance letters are not legally binding and do not impose obligations under the CSA or otherwise. *See Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 808 (D.C. Cir. 2006) (National Highway Traffic Safety Administration letters with "policy guidelines" "are nothing more than general policy statements with no legal force. They do not determine any rights or obligations, nor do they have any legal consequences."). The Justice Department confirmed as much months after the MOA was signed, stating that agency "guidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch." Davison Decl. Ex. 19 Nov. 16, 2017 Memo 1. As to the second admission, Plaintiffs do not even address it in their brief. And for good reason: it has nothing to do with suspicious order monitoring or Ohio.

3. Plaintiffs Cite No Record Evidence That Mallinckrodt's Suspicious Order Monitoring Program Was Deficient In Any Way After 2012.

Notably, Plaintiffs do not even attempt to show that Mallinckrodt's suspicious order monitoring program was deficient after 2012; none of the purportedly "undisputed facts" they cite relate to any conduct after 2012. Nor could they.

The undisputed evidence shows that Mallinckrodt was not only meeting but surpassing DEA requirements in various ways by 2012, and, in fact, well before then. First, as early as 2010, Mallinckrodt's anti-diversion program included voluntary monitoring of chargeback data. Gillies Tr. 221:7-18. Mallinckrodt reported to DEA the results of its monitoring. Harper Tr. 374:10-17. Second, as discussed above, Mallinckrodt invented a mechanism to deter potential diversion by restricting chargeback payments to its customers for sales to certain pharmacies about which Mallinckrodt had concerns. Davison Decl. Ex. 16; Davison Decl. Ex. 17. Third, Mallinckrodt had an algorithm that flagged potentially suspicious orders for investigation in accordance with regulatory requirements and reported orders to DEA twice a day.[28] Indeed, in response to learning about Mallinckrodt's chargeback review initiative, the St. Louis DEA Diversion Program Manager told Mallinckrodt that it had "the ***best*" *process that he had seen to date*** and ***"what he expected from Mallinckrodt as an industry leader***." Davison Decl. Ex. 26 November 1, 2010 Harper Notes from DEA St. Louis Meeting (MNKT1_0000421974).

Tellingly, both experts retained by Plaintiffs to opine on the alleged insufficiency of Defendants' controlled substances compliance programs conceded that they were not offering any opinion that Mallinckrodt's anti-diversion program was insufficient or ineffective after 2012.

[28] Davison Decl. Ex. 12 2012 SOM Policy; Davison Decl. Ex. 20 May 6, 2013 AM SOM Report (MNK-T1_0002216027); Davison Decl. Ex. 21 May 6, 2013 PM SOM Report (MNK-T1_0002217298); Davison Decl. Ex. 22 May 7, 2013 AM SOM Report (MNK-T1_0002217300); Davison Decl. Ex. 23 May 7, 2013 PM SOM Report (MNK-T1_0007708172); Davison Decl. Ex. 24 May 8, 2013 AM SOM Report (MNK-T1_0002217304); Davison Decl. Ex. 25 May 8, 2013 PM SOM Report (MNK-T1_0002217306).

Rafalski Tr. 665:19-666:8 ("Q: Okay. So fair to say in this litigation, you're not providing any opinion with respect to Mallinckrodt's suspicious order monitoring program after 2011? . . . A: . . . so that would be an accurate statement as of today."); Whitelaw Tr. 938:9-13 ("Q: Are you stating today that you cannot offer an opinion as to the adequacy of Mallinckrodt's anti-diversion program post 2012? A: That is what I'm saying. . . ."). This Court should deny Plaintiffs' motion for partial summary judgment for any claim past 2012 on this basis alone.

B. Purdue Complied With Its Obligations Under The CSA

Plaintiffs broadly claim that Purdue failed to maintain and operate a SOM system, use available data to identify suspicious orders, report suspicious orders to the DEA, or stop shipments of suspicious orders pending investigation. Mot. at 37. The discovery record simply does not support Plaintiffs' theories. Neither Plaintiffs nor their experts identify a single suspicious order that Purdue failed to investigate or report, or identify a single Purdue order that was diverted in the Plaintiff counties. In fact, Plaintiffs' brief describes certain components of Purdue's system and actions taken by Purdue to identify, investigate, and report orders under the system. Plaintiffs do not, however, accurately detail Purdue's SOM program in the 3 ½ pages of briefing focused on Purdue. They fail to acknowledge that Purdue's suspicious order monitoring practices evolved over time as the DEA's interpretation of the CSA evolved. Plaintiffs fail to recognize that Purdue revised and expanded its suspicious monitoring practices in 2008 to help its direct customers (i.e., wholesalers and distributors) monitor their customers (i.e., retail pharmacies) by putting in place an Order Monitoring System ("OMS"), while Purdue continued to monitor orders from the distributors consistent with their actual regulatory obligations. Plaintiffs cherry-pick snippets from a few documents in aid of their extraordinary request for a pre-trial ruling that Purdue's SOM program was legally inadequate for the entire time period relevant to this case. Genuine disputes

of material fact as to Purdue's suspicious order monitoring activities make summary adjudication improper.

First, while Plaintiffs baldly assert Purdue failed to maintain and operate a SOM system, Plaintiffs acknowledge Purdue has had a suspicious order monitoring system in place since at least the early 2000s. This alone creates a genuine fact issue. Plaintiffs do not dispute that Purdue implemented a suspicious order monitoring system and had controls in place to monitor orders received directly from wholesale distributors. Purdue held an order for review if it fell outside certain established parameters (e.g., exceeded a set amount as compared to the customer's prior orders) and independently reviewed the order. Pls. Ex. 88 (Dkt. 1944–88); Seid Tr. 317:01–05 (Dkt. 1970–20/1984–13). The governing procedures established that if the legitimacy of the order was not otherwise verified, a determination was to be made about whether further investigative steps were required, and if the findings should be reported to the DEA. Pls. Ex. 88.

Plaintiffs' attack goes to the effectiveness of Purdue's system, and whether Purdue could have done more to review and investigate held orders. Plaintiffs allege that the focus of Purdue's monitoring system involved "financial considerations" and that a Purdue employee released held orders too "quickly." Mot. at 37–38. But those are not legal issues for this Court to decide. There is testimony to the contrary, and it is for a jury to evaluate and weigh that testimony.

On this front, it is telling that Plaintiffs make no attempt to cite any specific deposition testimony—apart from a generic citation to entire deposition transcripts—from Steve Seid, who was Director of National Accounts and Trade Relations for a portion of the relevant time period. Mr. Seid testified for two days in his individual capacity and as a Rule 30(b)(6) witness. He detailed the steps taken and factors considered by Purdue when reviewing a held order, such as: reviewing the customer's ordering patterns; reviewing overall sales for the account; considering

whether the customer was a regional distribution center; considering the strength of OxyContin ordered; consulting with the manager responsible for the account; communicating directly with the customer; and determining if there were any changes in health coverage to the area. Seid Tr. 317:23–318:08, 320:13–21, 326:15–327:03, 327:21–22. In one instance, Mr. Seid released an order shortly after it was flagged because he was already familiar with the account and knew that the wholesaler was ordering inventory of the lowest dosage of OxyContin to be distributed to the company's 26 regional distribution centers. *Id.* at 326:08–20. Again, this is a fact issue inappropriate for summary adjudication.

Plaintiffs' reliance on a single instance of flagged orders placed by distributor Anda similarly does nothing more than highlight a dispute between Plaintiffs' mischaracterizations and the actual contents of the document featured in Plaintiffs' brief. Mot. at 38. A close and fair review shows that Purdue ***did*** engage in due diligence before it released the orders. Purdue contacted Anda's buying group to understand the reasons for the increased orders. Mr. Seid and others had internal discussions about the orders. Pls. Ex. 77 (Dkt. 1944–77); *see also* Seid Tr. 235:02–12, 237:20–22. Finally, Plaintiffs' citation to a 2003 version of Purdue's SOP No. 7.7 ("System to Disclose Suspicious Orders of Controlled Substances") ignores that Purdue continually revised and updated its SOPs related to suspicious order monitoring, including in March 2009, September 2017, and January 2018. Gonzalez Decl. Ex. 27 March 2009 GC-SOP-7 (PPLPC031001491482); Gonzalez Decl. Ex. 28 Sept. 2017 CC-SOP-17 (PPLP004368538); Gonzalez Decl. Ex. 29 Sept. 2017 CC-SOP-18 (PPLP004393084); Gonzalez Decl. Ex. 30 Jan. 2018 CC-SOP-19 (PPLPC023000971890).

Second, Plaintiffs attempt to invent new legal obligations with the suggestion that Purdue's access to certain data reflecting downstream transactions—i.e., information on Purdue's

customers' customers and Purdue's customers' customers' customers—obligated Purdue as a matter of law to use that information to monitor and report downstream pharmacies and individual prescribers (including "Region 0" prescribers). Mot. at 38–40. This obligation is not required by any statute or regulation. *See supra* Section II.D. Even if Purdue were required to use these data to monitor the sales and shipments of its customers to downstream pharmacies and the decisions of its customers' customers to fill individual prescriptions—which Purdue is not—the data are more limited than Plaintiffs make it seem. Jack Crowley, former Executive Director of Compliance, explained that IMS data do not reveal prescriber data at the pharmacy level. If those data were to become available and if they could be combined with other available SOM data, pharmacy-level prescriber data would be the "holy grail" of information. Crowley Tr. 153:15–17, 156:08–12, 158:05–159:02 (Dkt. 1961–8/1976–8). In addition, Purdue did not have real-time data regarding downstream purchases. Rafalski Tr. 718:12–719:02; *see also* Pls. Ex. 87 (Dkt. 1944–87) (noting limitations of Purdue's OMS system due to significant data gaps).

Third, Plaintiffs claim that Purdue failed to report suspicious orders to the DEA. Mot. at 37, 40. Plaintiffs again distort Purdue's legal obligations by insinuating that manufacturers have a duty under the CSA and related regulations to monitor and report downstream activity. Manufacturers have no such duty. That aside, Purdue was "routinely" in communication with the DEA and distributors about potentially suspect pharmacy accounts. Crowley Tr. 146:09–15, 287:19–25. At least as early as 2008, the Purdue OMS Committee (an inter-disciplinary group including high-ranking staff from the Legal, Compliance, National Accounts, and Corporate Security Departments) worked to identify potentially problematic dispensing pharmacies based on data-based algorithms. Gonzalez Decl. Ex. 31 May 2012, Purdue Committee Charters at 45 (PPLPC012000378036); Pls. Ex. 87; Gonzalez Decl. Ex. 27 March 2009 GC-SOP-7

(PPLPC031001491482); Crowley Tr. 67:14–20. The Committee was empowered to review sales data, discuss with wholesalers, analyze Abuse and Diversion Detection (ADD) reports, review publicly available information, and surveil the site to determine whether a referral was warranted. Gonzalez Decl. Ex. 32 Purdue Order Monitoring System (PPLPC019001275418); Gonzalez Decl. Ex. 31 May 2012, Purdue Committee Charters at 45 (PPLPC012000378036). Purdue's general policy was to address information of concern with the distributor first. Gonzalez Decl. Ex. 27 March 2009 GC-SOP-7 (PPLPC031001491482); Crowley Tr. 89:17–90:09, 95:02–05, 97:20–22. However, Purdue also had the option to independently report suspicious pharmacy activity and did so on a number of occasions. Crowley Tr. 95:06–10. For instance, in October 2011, Purdue reported to the DEA nearly 300 "slow pharmacies" whose orders had drastically declined following the reformulation of OxyContin, leading Purdue to believe they previously had been inappropriately dispensing the original formulation. Pls. Ex. 87; Gonzalez Decl. Ex. 33 Oct. 7, 2011 Email from J. Crowley to DEA (PPLPD004687363). Since that time, Purdue has referred to the DEA dozens of additional downstream customers. Gonzalez Decl. Ex. 34 Dec. 2017, Ethics & Compliance/Legal Presentation: SOM End of Year Review at 6 (PPLPC021000923153) (reporting that 46 downstream customers were referred to the DEA based on Q1 and Q2 data in 2017 alone). Purdue also met with the DEA on several occasions—including in April 2009, April 2011, and October 2011—to discuss its OMS program. Pls. Ex. 87; Gonzalez Decl. Ex. 33 Oct. 7, 2011 Email from J. Crowley to DEA (PPLPD004687363).

Fourth, Plaintiffs claim that Purdue failed to stop shipments of suspicious orders, but then acknowledge at least one instance where Purdue did just that. Mot. at 40. Plaintiffs' DEA expert, James Rafalski, admitted there was "due diligence conducted by the company" with respect to

suspicious orders. Rafalski Tr. 779:18–24. And in any event, Purdue has no legal or regulatory obligation to stop shipments to downstream customers.

There is no dispute that Purdue had in place a SOM program, and did in fact investigate, suspend, and report suspicious orders and accounts under that program. Plaintiffs' Motion describes a robust suspicious order monitoring program, and at most raises factual issues that cannot be decided through Plaintiffs' extraordinary request for summary adjudication.

C. The Teva Defendants Complied With Their CSA Duties As A Matter Of Law

After extensive discovery, Plaintiffs still cannot point to a single suspicious order that Cephalon, Teva USA, or any other affiliated entity failed to identify, investigate, report, or halt. Mot. at 41–43; Dkt. 1784 at 15–17. Further, Plaintiffs' motion simply refers to all such entities as "Teva," without distinguishing between the conduct of any specific one; indeed, Plaintiffs' motion does not expressly reference Cephalon, Teva USA, or any of the generic manufacturers ("Actavis Generic Entities") that Teva USA became affiliated with in 2016. For these reasons, summary judgment must be denied as to them.

But Plaintiffs' motion fails for another, even more fundamental reason: these entities complied with the CSA.[29] The full record—as opposed to Plaintiffs' out of context cherry-picked points—establishes that Cephalon and Teva USA ("Teva Defendants") always had SOM systems in place to identify and report any suspicious orders placed by their customers, took additional steps to detect and prevent diversion, and fully complied with their CSA obligations. Nor did they

[29] Cephalon integrated its SOM system with Teva USA's SOM system after it became affiliated with Teva USA in October of 2011. Reed Decl. Ex. 35 C. McGinn Decl. ¶ 7. Likewise, in August 2016, the Actavis Generic Entities became affiliated with Teva USA and, shortly thereafter, the Actavis Generic Entities' generic controlled substances acquired through the transaction were integrated into Teva USA's SOM system. (*Id.* ¶ 13.) Although Plaintiffs appear to focus on Teva USA and do not expressly address the conduct of the Actavis Generic Entities in their motion (an independent ground for denial), any such arguments as to the Actavis Generic Entities after August 2016 fail for the reasons set forth in this section. Likewise, Plaintiffs' motion as to the Actavis Generic Entities (former subsidiaries of Allergan plc) prior to August 2016 fails for the reasons set forth by Allergan in its section. *See* Section IV.E.

receive any communications from the DEA regarding any problems with their SOM systems or the failure to report orders. Despite their efforts to invent legal requirements that simply do not exist, Plaintiffs cannot show a breach of any duty.

1. Cephalon And Teva USA Have Always Had Fully Compliant SOM Systems In Place And Took Sufficient Steps to Prevent Diversion.

Plaintiffs do not and cannot argue that Cephalon failed to comply with and CSA duties, and they acknowledge that Teva USA had electronic SOM systems in place to identify and report suspicious orders. (Mot., at 41–43.) Instead, Plaintiffs merely argue, with the skewed benefit of hindsight, that the Teva Defendants' SOM systems could have been different. (Mot. at 40–42.) That is not the standard nor the law. The applicable regulation states that the "registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). That is what the Teva Defendants did—and much more.

Cephalon has always had a DEA Compliance department, along with an SOM process in place to identify, investigate, and, if necessary, report to the DEA suspicious orders of the only two opioids it manufactured and sold (Actiq and Fentora). Reed Decl. Ex. 35 C. McGinn Decl. ¶¶ 5–6. Notably, prior to acquisition by Teva USA in 2011, Cephalon had an exclusive distributor, Cardinal. Cardinal had an SOM system in place to monitor and report any suspicious orders from its customers. (*Id.*) Further, since 2012, all "wholesalers/distributors" of Actiq and Fentora have had to comply with the stringent requirements of the TIRF REMS Program, which, among other things, requires each such entity to "verify the current enrollment of a pharmacy in the TIRF REMS Access program prior to distributing a TIRF medicine to that pharmacy." Reed Decl. Ex. 36 TIRF REMS Access Program, Wholesaler/Distributor Enrollment Form, p.1.[30]

[30] Pharmacies, in turn, must receive education on the risks and approved uses of those medicines, and can only dispense those Actiq or Fentora prescriptions written by enrolled providers to enrolled patients. (Reed Decl. Ex. 38

Like Cephalon, Teva USA has always had controls in place to prevent the theft or diversion of opioids. Reed Decl. Ex. 35 C. McGinn Decl.. ¶ 9; Reed Decl. Ex. 37 J. Tomkiewicz Decl. ¶ 5. It has utilized an SOM system to monitor, identify, and, if necessary, report suspicious orders to the DEA. Reed Decl. Ex. 35 C. McGinn Decl. ¶ 10. For more than a decade, Teva USA has used computer software, with proprietary algorithms, to review all orders based upon specified parameters. *Id.* ¶ 11. Each of those systems (known as SORDS, SORDS II, and DefOPS) evaluated average purchase quantities for each customer for each ordered product and then automatically pended orders that deviated from the customer's normal purchasing pattern—subject to a detailed investigation by the DEA compliance team. After investigation, any order deemed "suspicious" was reported to the DEA. *Id.* ¶ 11; Reed Decl. Ex. 37 J. Tomkiewicz Decl. ¶ 9.

Teva USA also has continuously updated its SOM systems and investigation protocol. In 2014, for instance, Teva USA developed an enhanced SOM system, called Defensible Order Pended System ("DefOPS"),[31] which it implemented in early 2015. Reed Decl. 35 C. McGinn Decl. ¶ 12; Reed Decl. Ex. 37 J. Tomkiewicz Decl. ¶ 8. This advanced system uses a sophisticated algorithm to identify specific orders (such as those potentially unusual size or frequency) that require further analysis, based upon order history of specific drug class, active ingredient by weight in grams, and customer peer group. Reed Decl. Ex. 35 C. McGinn Decl. ¶ 12; Reed Decl. Ex. 37 J. Tomkiewicz Decl. ¶¶ 8–9. Teva USA also enhanced its efforts to investigate to understand if there are legitimate explanations for any such order. Reed Decl. Ex. 37 J. Tomkiewicz Decl. ¶¶

"Frequently Asked Questions," TIRF REMS Access Manual, undated, available at https://www.tirfremsaccess.com/TirfUI/rems/pdf/faq.pdf, pp. 2–3.) Notably, wholesalers and distributors are also required to acknowledge that they comply with other requirements, including that they will cooperate with periodic audits and that relevant staff are trained on, and will follow, the TIRF REMS Program. (Reed Decl. Ex. 36 TIRF REMS Access Program, Wholesaler/Distributor Enrollment Form, p.1.)

[31] Grasping at straws, Plaintiffs take issue with the name of Teva USA's SOM system—which, of course, has no bearing on the efficacy of the system and whether it complies with CSA requirements.

8–9. Once again, while Plaintiffs argue in hindsight that Teva USA could have done more, that is not the standard. The Teva Defendants fully complied with their CSA duties. *Id.* ¶ 19.

2. Plaintiffs' Hindsight Arguments Ignore The Factual Record.

Plaintiffs nonetheless make the hindsight argument that the "inadequacy of Teva's system is confirmed by the fact that even after it implemented a written SOMs' policy [in 2014], it reported and stopped very few suspicious orders." Mot. at 42. But that is not evidence of anything and ignores the factual record.

As to Cephalon, because it manufactured only two opioid medicines with narrow indications, Cephalon had relatively few orders placed by very few customers—all of which had a longstanding relationship with Cephalon. Reed Decl. Ex. 35 C. McGinn Decl. ¶ 6. As to Teva USA, its customers were predominantly wholesale distributors (not pharmacies) that had their own SOM systems in place to monitor their own customers' suspicious orders. Reed Decl. Ex. 37 J. Tomkiewicz Decl. ¶ 10. Teva USA also knows its customers and their order patterns, and evaluates any new customer before any shipment occurs. (Id.) As a result, it is not surprising that Teva USA reported few suspicious orders from its customers. Moreover, Teva USA did in fact identify and report any orders to the DEA that were suspicious—the number of which increased after 2016, once Teva USA became affiliated with the Actavis Generic Entities and integrated their generic products into Teva USA's SOM system. Reed Decl. Ex. 35 C. McGinn Decl. ¶ 13; Reed Decl. Reed Decl. Ex. 37 J. Tomkiewicz Decl. ¶¶ 13, 15, 18.

Finally, Plaintiffs have not identified a single suspicious order—before or after 2014—that Teva USA, Cephalon, or any of the Actavis Generic Entities failed to report. This alone is dispositive. Plaintiffs cannot provide evidence of the breach of any CSA duty by the Teva

Defendants or the Actavis Generic Entities if they cannot identify a single suspicious order that they failed to report (much less one that was shipped to Ohio)—the very essence of their claims.

3. Plaintiffs Cannot Invent New Legal Requirements, Much Less Obtain Summary Judgment, Based Upon Their Mischaracterization Of Two Non-DEA Documents.

Plaintiffs argue that Teva USA did not comply with its duties because it did not have formal written policies regarding its SOM program before September 2012. Mot. at 40–41. Not so. Plaintiffs do not and cannot dispute that both Cephalon and Teva USA had active SOM programs in place, and there is no requirement in any regulation that an SOM procedure must be written. DEA has conceded this point.[32]

Plaintiffs' next argument is that summary judgment is appropriate because while Teva USA had an SOM system in place, the sales department played a role in the investigation of flagged orders. Mot. at 41. This argument fails as a matter of law and common sense. There is no legal requirement in the CSA or its regulations that the customer service department cannot be part of the investigation process. Further, regardless of whether Plaintiffs believe it was appropriate to seek input from personnel who may be most knowledgeable about the company's customers, the DEA Compliance department made all final determinations as to whether an order was suspicious. Reed Decl. Ex. 37 J. Tomkiewicz Decl. ¶ 12. Customer service representatives (not sales representatives as Plaintiffs claim) only gathered information from customers with whom they had prior contact. *Id.* Plaintiffs simply ignore that the customer service representatives were in the

[32] *See* Prevoznik Tr. Vol. 1 358:21–359:1 ("Q: Does it say anywhere in the relevant regulations that registrants are required to have a written policy with respect to suspicious order monitoring? A: No."); Reed Decl. Ex. 39 Colder Rpt. 11 ("DEA did not provide meaningful guidance to registrants seeking more information on how to comply with their suspicious order monitoring obligations, leaving interpretation to the discretion of individual registrants."); *id.* at 15 ("[N]or is there any requirement that a registrant must have written policies and procedures with respect to suspicious order monitoring.").

best position to gather such information, as they had knowledge of the customer's facilities, past practices and orders. *Id.*

Unable to identify any specific CSA duties that the Teva Defendants breached, Plaintiffs focus on two SOM-related documents from 2012 and 2015. Plaintiffs argue that a 2012 report from Cegedim Compliance Solutions ("Cegedim"), a consulting company that Teva USA hired to review its SOM system at the time, was "starkly critical." Mot. at 40. But while that report identified potential areas of improvement, it expressly stated that Teva USA has the "essential elements" for an SOM program. Pls. Ex. 98 at 1. It did not find that Teva USA failed to comply with any legal duties or failed to identify any suspicious orders. *Id.* Moreover, that report was written by a company with the motivation of having Teva USA purchase Cegedim's own proprietary SOM system. Reed Decl. Ex. 35 C. McGinn Decl. ¶ 14. And contrary to Plaintiffs' suggestions, Teva USA decided not to use Cegedim's SOM system because Cegedim refused to disclose its algorithm, which would have deprived Teva USA of the ability to analyze the efficacy of its system and to understand any changes that needed to be made. *Id.* This shows good practice—not a breach of any duty.

Lastly, Plaintiffs point to a 2015 internal audit done by Teva USA's parent company which "focused primarily on the fact that suspicious orders were cleared through the decisions of a single person (Tomkiewicz), which exposed the system to the risk of mistaken releases." Mot. at 42. Once again, there is no legal requirement that prevents this type of review or that dictates a certain number of people must review flagged orders. Moreover, once again, Plaintiffs ignore the critical, undisputed fact that discovery has failed to identify a single "mistaken release" by Teva USA. Reed Decl. Ex. 37 J. Tomkiewicz Decl. ¶ 15. In light of Teva USA's relatively low volume of orders of controlled substances at the time, the system for reviewing orders in place was

reasonable. *Id.* Since August 2016, when Teva USA became affiliated with the Actavis Generic Entities (and their portfolio of generic medicines), the volume of orders of controlled substances necessarily increased, and, as a result, Teva USA added additional levels of review (involving multiple people) of any flagged orders. *Id.* ¶ 15. In short, summary judgment in favor of Plaintiffs is inappropriate as to the Teva Defendants (or any of the Actavis Generic Entities). *Id.* ¶ 19.

4. The DEA Has Never Communicated Any Problems to the Teva Defendants About Their SOM Systems or Any Suspicious Orders.

Plaintiffs also ignore that the DEA has never communicated to the Teva Defendants that their SOM systems did not comply with applicable law, much less that they failed to properly report suspicious orders. Reed Decl. Ex. 35, C. McGinn ¶¶ 8, 15; Reed Decl. Ex. 37, J. Tomkiewicz Decl. ¶¶ 16, 18.) While the DEA has taken action against other registrants, it has never taken any enforcement action against Cephalon or Teva USA (or any of the Actavis Generic Entities) for any alleged failure to maintain diversion controls. Reed Decl. Ex. 35, C. McGinn ¶¶ 8, 15; Reed Decl. Ex. 37, J. Tomkiewicz Decl. ¶ 16; Reed Decl. Ex. 39, Colder Rpt. 34 n.97 (Dkt. 1939-10/1936-10). This evidence further shows why Plaintiffs' motion for summary judgment as to the Teva Defendants (and any of the Actavis Generic Entities) fails.

D. Janssen Complied With Its Obligations Under The CSA

Plaintiffs' arguments about Janssen omit the overwhelming evidence that, in fact, Janssen's suspicious order monitoring program met all legal requirements under the CSA. Janssen, not Plaintiffs, is entitled to summary judgment as to the sufficiency of its program. *See* Janssen MSJ 9-11 (Dkt. 1919-1). Unable to show that Janssen's program was legally deficient, Plaintiffs instead

recite various criticisms of Janssen's program that have no basis in law and cannot support their motion.[33]

1. Janssen's Perfect DEA Inspection Record of Its Suspicious Order Monitoring Program Is Sufficient to Defeat Summary Judgment

Janssen's perfect compliance record following numerous multi-day DEA inspections since 2006 alone would permit a reasonable jury to conclude that Janssen's suspicious order monitoring program complied with the CSA. Janssen provided the standard operating procedures for its suspicious order monitoring program to the DEA on several occasions in connection with DEA inspections.[34] And none of these many inspections revealed a single failure or deficiency.[35] In fact, DEA inspectors repeatedly praised Janssen's CSA compliance. After one inspection, the DEA had "nothing but positive feedback" for Janssen. Cardelus Decl. Ex. 43. At the conclusion of another visit, a DEA inspector noted that "[t]his close-out will be short and sweet"; the inspection had zero observations (*i.e.*, negative findings). *Id.* Ex. 45. Yet another DEA inspection found "no CFR violations"; one DEA inspector in attendance remarked that he "likes coming to places like this." *Id.* Ex. 40.

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[33] In the Complaints, Plaintiffs improperly lump Noramco, Inc. together with Johnson & Johnson and its other affiliated entities, all Marketing Defendants, or all Defendants collectively. For this reason, Noramco joins this opposition even though it never manufactured, packaged, branded, marketed, promoted, distributed or sold the finished drug products that are at issue in this litigation. Indeed, as Plaintiffs concede in their own brief, there is no evidence that Noramco engaged in any wrongful conduct that might give rise to liability (see also Noramco's Memorandum in Support of Motion for Judgment on the Pleadings or, in the Alternative, Summary Judgment, Dkt. 1902-1), let alone that it had the duties Plaintiffs allege under the CSA or that it breached those alleged duties. Specifically, in their Memorandum of Law, Plaintiffs proclaim that the inclusion of Noramco as a defendant was an afterthought, stating in a footnote that Noramco was not "mentioned in the documents with respect to the SOMS program" and that Plaintiffs "improperly grouped all the J&J defendants in [their] MSJ as 'Janssen' and [] provided no evidence for Noramco." Dkt. 1924-1 at 54 n.129.

[34] *See, e.g.*, Dempsey Tr. Vol. 2 601:2-16 (Dkt. 1961-13/1976-13); Cardelus Decl. Ex. 40 at 5 ("SOPs and overview" of suspicious order process provided during 7/13 inspection), Ex. 41 ("Suspicious Order Procedure" documents provided during 1/15 inspection), Ex. 42 ("Suspicious Order SOP" provided during 8/15 inspection), Ex. 43 ("All written policies or procedures pertaining to Controlled Substances (i.e. Standard Operating Procedures)" provided during 12/17 inspection).

[35] *See, e.g.*, Dempsey Tr. Vol. 2 665:2-666:21, 678:5-23, 687:4-20, 697:4-15, 699:18-700:3; Cardelus Decl. Ex. 44 (12/08 inspection), Ex. 40 (7/13 inspection), Ex. 41 (1/15 inspection), Ex. 42 (7/15 inspection), Ex. 45 (8/15 inspection), Ex. 43 (12/17 inspection), Ex. 46 (12/17 follow-up inspection), Ex. 47 (9/18 inspection).

The many DEA inspectors who passed through Janssen's facilities would have informed Janssen had they observed any non-compliance, as both current and former DEA employees testified in this case. Prevoznik Tr. Vol. 1 290:8-20 (DEA inspects registrants' protocols and policies and would raise any concerns it had with the registrant); Cardelus Decl. Ex. 48 Mapes Tr. 50:23-51:7 (inspectors would "tell the registrant what that registrant was doing wrong" if they "determine[d] that a registrant was not complying with the regulations").

Janssen's DEA inspection record alone is sufficient to defeat Plaintiffs' motion for summary judgment. Indeed, it establishes *Janssen's* entitlement to summary judgment as to Plaintiffs' claims based on Janssen's suspicious order monitoring program. *See* Janssen MSJ 9-11 (Dkt. 1919-1). Plaintiffs themselves argue that the Court should defer to the DEA's application of its own regulations. *See, e.g.*, Mot. at 26 (contending that Plaintiffs are entitled to summary judgment as to other companies because of the DEA's negative findings). The DEA never once found Janssen's suspicious order monitoring program to be in violation of the CSA, and this should end the Court's inquiry as to Janssen.

2. The Evidence Concerning the Features of Janssen's Suspicious Order Monitoring Program Defeats Summary Judgment

Even setting aside Janssen's compliance record, Plaintiffs have offered no evidence establishing as a matter of law that Janssen failed to "design and operate a system to disclose . . . suspicious orders," defined as "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). The evidence shows that—at a minimum, if Janssen is not granted summary adjudication—there is a dispute of fact.

The DEA may deem "[s]ubstantial compliance" with CSA regulations sufficient to meet registrants' legal duties even when there may be weaknesses in a registrant's security measures. *Id.* § 1301.71(b). And, as Plaintiffs' own expert witness has testified, the sufficiency of a

suspicious order monitoring program depends on a variety of factors, including what medications a registrant sells and the sales volumes and abuse rates of those medications. Rafalski Tr. 732:15-738:8; *see also* 21 C.F.R. § 1301.71(b) (providing that "[t]he type and form of controlled substances handled" is relevant to the need for strict compliance with CSA regulations). Here, Janssen's market share in the relevant counties was less than one percent, *see* Keller Rpt. 16, and its medications have consistently shown abuse rates materially lower than other opioid medications, *see* Cohen Rpt. 40 (Dkt. 1939-9/1936-9); Moskovitz. Tr. Vol. 2 223:24-224:7 (1968-10/1982-6); Moskovitz Tr. Vol. 1 684:4-17 (Dkt. 1968-11/1982-7); Vorsanger Tr. 280:25-282:9, 298:21-299:4 (Dkt. 1971-17/1985-9). Particularly given these facts, Plaintiffs cannot establish that Janssen's suspicious order monitoring program was deficient as a matter of law.

Plaintiffs repeatedly attack the sufficiency of the algorithm that formed one part of Janssen's suspicious order monitoring program. Mot. at 55-62. But—as Plaintiffs' own expert admits[36]—the CSA does not mandate any particular features in an algorithm, *see* 21 C.F.R. § 1301.74(b) (mandating only an overall "system to disclose suspicious orders"), and this algorithm is only one element in Janssen's suspicious order monitoring program.

In addition, Janssen's algorithm appropriately identified "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b). It flagged for further review all orders that exceeded three times the customer's average order size for a particular opioid medication (determined by SKU) over the past year. Pls.

[36] *See* Rafalski Rpt. 12-13 ("Beyond requiring that a distributor must employ *some* Suspicious Order Monitoring System ('SOMS'), the federal regulations do not make explicit exactly what algorithm(s) the SOMS must use to identify suspicious orders, or exactly what due diligence efforts are required when investigating an order after it is identified as suspicious. For example, a distributor is not *required* to use the Monthly Total Rule or the Pharmacy Comparison Rule; ***it is free to design its SOMS using any algorithms and rules it believes will get the job done***." (emphasis added)).

Ex. 180 at 3. Plaintiffs argue that this algorithm "*only* monitored for orders of unusual size" and not for unusual pattern or frequency. Mot. at 55. Plaintiffs are incorrect.

Janssen's algorithm also flagged deviations in pattern and frequency for further investigation. One such deviation would be an order of a particular opioid medication that a customer had never purchased, or had not purchased in the previous year. The algorithm would detect such orders because the 12-month rolling average for those customers would be zero, and thus any order would exceed the relevant benchmark. *See* Pls. Ex. 180 at 3; Dempsey Tr. Vol. 2 628:5-629:24. DEA employee Thomas Prevoznik testified that these scenarios—*i.e.*, when a product is ordered infrequently or not at all and then suddenly takes off—might represent examples of suspicious order patterns. Prevoznik Tr. Vol 1 281:8-282:12.

Janssen's algorithm was also equipped to detect another deviation in ordering pattern—namely, changes in dosage strengths. Because the algorithm evaluated orders on a per-SKU basis (*e.g.*, 50 mg Nucynta separately from 100 mg Nucynta), it would detect shifts in ordering from weaker to stronger dosages, which is yet another example of potentially suspicious activity. As Plaintiffs' own experts acknowledged, these sorts of changes are shifts in pattern as defined by the CSA. Rafalski Tr. 719:17-721:9. In sum, Janssen's algorithm monitored for "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," 21 C.F.R. § 1301.74(b), which is why the DEA never once found Janssen's algorithm to be deficient even after reviewing it multiple times, *see supra* at 35 n.34.

Plaintiffs also ignore that, after running the algorithm, Janssen manually investigated any order that its algorithm had flagged. Pls. Ex. 180 at 3. This manual investigation included "looking through the ordering pattern, as well as the frequency . . . ." Dempsey Tr. Vol. 2 455:2-8. Janssen policies required employees to hold from shipment all flagged orders until a Janssen representative

investigated, contacted the customer if necessary, and received a satisfactory explanation that dispelled any questions about the legitimacy of the order. Pls. Ex. 180 at 3. In addition to holding the order from shipment, Janssen policies required employees to notify the DEA if the customer could not provide an adequate explanation. *Id.* at 5.

Plaintiffs identify a handful of orders flagged by Janssen's algorithm[37] that were shipped soon after being flagged (Mot. at 61 n.175), but they offer no evidence indicating that any of those orders was actually suspicious within the meaning of the CSA. Plaintiffs also present no evidence in support of their claim that Janssen "appear[s]" not to have investigated these orders before shipping. Mot. at 61.

Plaintiffs also note that Janssen's algorithm ran at 3:45 pm daily, Mot. at 60; orders placed after 3:45 pm had to be manually evaluated before shipments were released. But because it is undisputed that such orders were in fact evaluated, *see* Dempsey Tr. Vol. 2 459:4-16, this cannot support summary judgment against Janssen.

Finally, Plaintiffs ignore that Janssen performed a quarterly comparison of the quantity of controlled substances each distributor ordered with the quantity of other medications it ordered. Dempsey Tr. Vol. 2 148:7-149:1. Since 2013, Janssen has also held monthly compliance meetings for the review of "metrics, orders, [and] trends." Dempsey Tr. Vol. 2 638:12-18.[38]

[37] Contrary to Plaintiffs' position, an algorithmically flagged order is not "suspicious" within the meaning of the CSA once it has been investigated and cleared by a registrant's employee. *See Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 216-17 (D.C. Cir. 2017) (holding that DEA's position that a particular registrant's algorithmically flagged orders "met the regulatory definition of 'suspicious orders' *unless [the registrant's] staff dispelled the suspicion*" was reasonable (emphasis added)).

[38] Plaintiffs contend that Janssen's suspicious order monitoring program is deficient because Janssen's monthly and quarterly reviews do not stop orders from shipment. Mot at 56. As discussed in Manufacturers and Distributors' joint brief, there is no stop-shipment requirement under the CSA. And even if there were, Janssen's monthly and quarterly reviews provide suspicious order controls *in addition to* Janssen's algorithmic and manual review, which *can* stop shipments in real time.

A reasonable jury could easily conclude from this evidence that Janssen satisfied its duties under the CSA, particularly in light of the miniscule market share and low abuse rates of Janssen's opioid medications. Plaintiffs cannot show that Janssen's suspicious order monitoring program was deficient as a matter of law.

3. Plaintiffs Cannot Establish that Janssen's Program Was Deficient by Pointing to "Missing" Features That the CSA Does Not Require

Because they cannot show that Janssen's program fell short of the standards set forth in the CSA, Plaintiffs instead attempt to measure Janssen's program against standards of their own creation. They complain that Janssen did not employ "chargeback data, wholesalers' inventory and sales data, and third-party data from Integrichain and ValueTrak." Mot. at 57. But, as explained above, there is no legal requirement that registrants use such data. *See supra* at Section II-D. Additionally, Janssen did use ValueTrak data during its monthly compliance reviews beginning in 2013. Dempsey Tr. Vol. 1 132:18-134:11 (Dkt. 1961-12/1976-12).

Plaintiffs also claim that Janssen's suspicious order monitoring program was deficient because Janssen did not conduct an internal workshop related to suspicious order monitoring or engage an outside consultant[39] before December 2017, Mot. at 60. Plaintiffs cite no authority to indicate that these are requirements for registrants under the CSA—because they are not.

Plaintiffs also contend that certain Janssen correspondence shows a "work[]around" to evade the suspension of the DEA registrations of several McKesson distribution centers. Mot at 61-62. As an initial matter, this claim has nothing to do with the sufficiency of Janssen's

[39] Janssen engaged this consultant in anticipation of the release of a non-opioid Schedule III medication for the treatment of depression—not because of any deficiencies flagged by DEA or concerns about opioid medications. Pls. Ex. 193 at 14. The consultant concluded that Janssen's program complied with the CSA and offered suggestions to enhance it further. *Id.* at 2-3.

suspicious order monitoring program.[40] In addition, Plaintiffs misrepresent this correspondence, which in fact demonstrates Janssen's efforts to *comply with* DEA regulations and states that Janssen sent all opioid shipments to licensed McKesson facilities. Pls. Ex. 208. The DEA explicitly approved similar actions by Janssen in connection with the suspension of Cardinal Health distribution centers. Cardelus Decl. Ex. 49. Plaintiffs cite no evidence supporting their claim that Janssen "kn[ew] that its controlled substances would eventually reach . . . centers [that] could no longer sell controlled substances," Mot. at 62, because no such evidence exists.

4. The Absence of Suspicious Order Reports Does Not Mean Janssen's Suspicious Order Monitoring Program Was Deficient

Finally, Plaintiffs argue that Janssen's suspicious order monitoring program was deficient because Janssen did not report any suspicious orders to the DEA. Mot at 60-61. Not so. Plaintiffs have presented no evidence that any suspicious orders existed; to the contrary, Plaintiffs' experts opined that they could not identify any such orders. Rafalski Tr. 631:13-634:2; Keller Tr. 49:3-8, 55:23-56:25. The lack of suspicious orders is unsurprising: Janssen's opioid medications accounted for less than one percent of the opioid market in the Track One counties, and Janssen opioid medications were abused at much lower rates than other opioid medications. Indeed, there is no such thing as a "patch mill," and there is not a shred of evidence anywhere that tapentadol—which was specifically designed to be difficult to misuse—was subject to widespread abuse.

In sum, the evidence shows the sufficiency of Janssen's suspicious order monitoring system. If the Court does not grant Janssen's motion for summary judgment, this issue must go to the jury.

[40] Such programs are for the detection of "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74(b). Separate provisions of the CSA—which are not the subject of Plaintiffs' motion for summary judgment—forbid shipments to buyers without DEA registrations.

E. Allergan Complied With Its Duties Under The CSA

While unable to assert a single fact against Allergan to establish that it violated the CSA or its implementing regulations, Plaintiffs nonetheless makes baseless claims about Allergan's legacy Actavis and Watson systems in support of its Motion.

First, Plaintiffs claim that the SOM system used by pre-merger Actavis failed to maintain effective controls against diversion.[41] Specifically, Plaintiffs argue that the Actavis system "did not utilize any downstream customer information available to Actavis."[42] Evidence is to the contrary: Actavis purchased a product from ValueCentric in 2011 that monitored downstream customer information by tracking 867 data.[43] Witnesses also testified that Actavis utilized chargeback data (downstream customer information) in connection with its SOM program,[44] and developed a Standard Operating Procedure for monitoring downstream customer information.[45] While Plaintiffs assert this SOP was "never implemented,"[46] it ***was*** implemented, and Actavis monitored downstream customer information even before this SOP was finalized.[47] And, Plaintiffs mischaracterize Doug Boothe's testimony on the Actavis SOM system. Plaintiffs claim that Mr. Boothe said the company had "no responsibility (or accountability) for preventing diversion" generally. Not so. Mr. Boothe accurately testified that the company did not have "responsibility for, accountability for preventing diversion . . . ***once [the product] goes outside of our chain of custody***."[48] Plaintiffs distort this testimony knowing full well that Mr. Boothe was

[41] Mot. at 63.
[42] *Id.*
[43] Knapp Decl. Ex. 50 (ALLERGAN_MDL_01451450).
[44] *See, e.g.*, McCormick Tr. 189:9-18 (Dkt. 1966-19/1981-14).
[45] Knapp Decl. Ex. 51 (ALLERGAN_MDL_01979834).
[46] Mot. at 64 n.187.
[47] *See* Baran Tr. 335:21-336:1 (Dkt. 1956-13/1974-13) ("Q: Was the indirect suspicious order monitoring process ever implemented at Actavis prior to the Watson acquisition? A: Yes."); Knapp Decl. Ex. 52 (Acquired_Actavis_01931815); Knapp Decl. Ex. 53 (Acquired_Actavis_00780400); Knapp Decl. Ex. 54 (Acquired_Actavis_00488498).
[48] Mot. at 66.

correct: there is no legal obligation for a manufacturer to monitor downstream, or "know it's customer's customer."[49] Plaintiffs also rely on an email from Nancy Baran discussing Actavis's "DEA Suspicious Report"—a document flagging controlled and non-controlled substance orders—as evidence that Actavis's SOM program was inadequate.[50] But Ms. Baran testified that she did not have concerns about whether Actavis was flagging suspicious orders as required by the CSA. Instead, her February 2009 email referenced that the report was being used for both SOM and routine inventory management, and also flagged orders of ***non-controlled substances***.[51] According to Ms. Baran, this "didn't impact the end result" for SOM monitoring purposes.[52] And while Plaintiffs criticize that orders flagged in Actavis's DEA Suspicious Report were not automatically held while the order was investigated,[53] Ms. Baran confirmed that orders were manually held until the investigation concluded,[54] and DEA witnesses testified that automation was not required.[55]

Plaintiffs refer to a DEA meeting with Actavis Elizabeth LLC held in 2012, and suggest that DEA was critical of Actavis's SOM, blaming Actavis for the diversion of oxycodone in Florida.[56] DEA's own internal memorandum states that the purpose of the meeting was "to inform, educate, provide pertinent ARCOS data, discuss national trends, and discuss the pain management epidemic in Florida involving oxycodone. The DEA is seeking to partner with drug distributors

[49] *See generally* Section II (explaining manufacturers had no duty to monitor orders after they are shipped).
[50] Mot. at 63 (citing ALLERGAN_MDL_02128035).
[51] Baran Tr. 253:10-256:12; Baran Tr. 122:1-12.
[52] Baran Tr. 122:1-12.
[53] Mot. at 64.
[54] Baran Tr. 79:23-80:10 ("The orders would be placed on -- on hold, that was manual. And then once we did our due diligence, if -- if we were satisfied with what we were releasing, the order of release would be manual."); *see also* Baran Tr. 247:5-11 ("Q: If there were a pended order, is it correct to say that you would investigate the nature of that order to conclusion prior to determining whether or not to cancel or ship the order? A: Yes.")
[55] *See* Prevoznik Tr. Vol. 1 180:12-15 ("Q: Does it matter to the DEA whether a registrant reviews orders manually or uses an automated system? A: No, it doesn't matter."); Ashley Tr. 88:11-13 ("Q: To your knowledge, does a legally compliant system need to be automated? A: No, it does not.")
[56] Mot. at 64-65.

and manufacturers in resolving this problem."[57] DEA also stated in that same memo that "if Actavis or any firm who had been briefed was found to have violated the CSA pertaining to what was discussed during the course of this meeting DEA could seek administrative or civil action to remedy the situation."[58] ***DEA never took any such action.*** Nor did DEA find (or even suggest) that Actavis was in violation of the law, or that its SOM program was noncompliant, or that DEA was contemplating any civil, criminal, or administrative proceedings against Actavis.[59] Plaintiffs' brief lists the suggestions DEA allegedly made to Actavis during that meeting,[60] but these were suggestions, Plaintiffs' own experts have testified that suggestions did not create legal obligations.[61] Ms. Baran, one of the attendees, testified that after this very same meeting, she had the impression that the DEA representatives "were very impressed" with Actavis's SOM program and that Actavis was actually "ahead of the curve" with respect to its SOM system and diversion control efforts.[62] Plaintiffs cite no record evidence to the contrary; this is because none exists, as DEA let registrants determine necessary requirements for their suspicious order monitoring systems rather than dictating those requirements.[63]

Plaintiffs also point out that Nancy Baran only remembered one order reported to the DEA as suspicious,[64] ostensibly to suggest that Actavis was underreporting. But Plaintiffs offer zero evidence that the company had any other orders determined to be suspicious after investigation, or that it failed to report. Even Plaintiffs' own SOM expert admitted that not every registrant will

[57] Pls. Ex. 496 at 4; *see also id.* at 1 (stating that the purpose of the meeting was "both educational and informative.")
[58] Pls. Ex. 496 at 4.
[59] Neither Actavis nor Watson ever received a reprimand nor any administrative action from the DEA about their SOM systems, though the DEA's 30(b)(6) witnesses testified that if the DEA determined a registrant's SOM system was not compliant, DEA "would take some sort of action." *See* Prevoznik Tr. 131:15-23.
[60] Mot. at 64-65.
[61] Prevoznik Tr. 370:14-23 ("guidance is not going to create a new rule"); 373:14-18 ("guidance is not imposing new requirements"); 374:5-9 (I don't believe guidance is -- any guidance is imposing new requirements.")
[62] Baran Tr. 272:10-24.
[63] *See* Section III (explaining that DEA left SOM system design up to the registrants).
[64] Mot. at 63.

have suspicious orders that will need to be reported to the DEA,[65] and Plaintiffs fail to identify even one order that Actavis should have reported as suspicious, but didn't.[66]

Plaintiffs next address the SOM system operated by pre-merger Watson, again arguing that Allergan's legacy systems were not in compliance with the law. According to Plaintiffs, Thomas Napoli, head of Watson's DEA Affairs team, "made clear that [Watson's SOM] system did not comply with the DEA laws and regulations," both through a 2008 memo summarizing a Controlled Substance Seminar sponsored by Cegedim/Buzzeo, and through his pursuit of a Cegedim/Buzzeo SOM system upgrade.[67] Plaintiffs' speculation is contrary to the record. Napoli's 2008 memo does not discuss, let alone criticize, Watson's SOM system. Rather, it summarizes a Controlled Substance Conference sponsored by a consultant, Cegedim, and a meeting of the New Jersey Pharmaceutical Industry Group.[68] When Napoli considered hiring Cegedim/Buzzeo to evaluate Watson's existing SOM program, he testified that "[i]t was an effort to enhance our ***already compliant system***."[69] Plaintiffs refer to the "findings" Cegedim made about Watson's SOM system,[70] but these "findings" are not law. Suggestions made by a third party company pitching the need for its services are not legally binding, and even if DEA itself had provided guidance, guidance does not create new law.[71]

Plaintiffs ignore evidence that also directly contradict Plaintiffs' characterization of the facts. For example, Plaintiffs state that the "automated portion of the [Watson SOM] system did

[65] Rafalski Tr. 591:18-592:8.
[66] *See* Section I.
[67] Mot. at 67-68.
[68] Knapp Decl. Ex. 55 (ALLERGAN_MDL_03535130).
[69] Napoli Tr. 136:22-23 (Dkt. 1968-16/1982-12); *see also* 190:6-9 (testifying that "***although we had a compliant system***, it was very labor intensive, and we were looking to make enhancements to the program that would sharpen the tool for us."); 323:7-12 ("I did believe that Buzzeo had a system that they were proposing that was compliant with the CFR. ***We also had one as well***, but we wanted to move up to a more enhanced sophisticated system.")
[70] Mot. at 68.
[71] Prevoznik Tr. Vol. 1 370:14-23 ("guidance is not going to create a new rule"); 373:14-18 ("guidance is not imposing new requirements"); 374:5-9 (I don't believe guidance is -- any guidance is imposing new requirements.").

not utilize any downstream customer information available."[72] But company policies and witnesses show that Watson utilized both 867 data and chargeback data (two types of "downstream customer information") in its SOM system.[73] While that data analysis was not automated, it was manually investigated by Watson employees, and DEA witnesses have themselves testified that there was ***no requirement*** that any part of a suspicious order monitoring system be automated.[74] Moreover, multiple DEA witnesses have testified that there was ***no requirement*** for manufacturers to monitor downstream customers at all.[75] Plaintiffs state that the multiplier used in Watson's SOM algorithm regularly allowed wholesalers, distributors, and chain pharmacies to order at "triple [300%] the historical average, or more."[76] This ignores evidence that the multipliers used by Watson frequently flagged orders made by wholesalers, distributors, and chain pharmacies that were only 25% or 50% above the customer's historical average.[77] Additionally, Plaintiffs complain that Watson's SOM staff did not expand or increase between 2009-2012 while the

[72] Mot. at 68-69.

[73] *See, e.g.*, Pls. Ex. 506 at -5581 (Watson policy indicating that one of the tools used during analysis of a pended SOMS order was 867 data); Knapp Decl. Ex. 56 Woods 30(b)(6) Tr. 149:3-150:10 (testifying that Watson utilized 867 data to evaluate orders); *Id.* at 151:22-152:9 (testifying that in addition to 867 data, Watson also conducted a monthly analysis of chargeback data); Woods Fact Tr. 62:5-9 (Dkt. 1972-11/1985-23) (same); Napoli Tr. 295:17-299:19 (explaining Watson's use of chargeback data as one tool to analyze customer ordering patterns).

[74] *See* Prevoznik Tr. 180:12-15 ("Q: Does it matter to the DEA whether a registrant reviews orders manually or uses an automated system? A: No, it doesn't matter."); *See* Ashley Tr. 88:11-13 ("Q: To your knowledge, does a legally compliant system need to be automated? A: No, it does not.")

[75] Ashley Tr. 159:20-161:8 (testifying that there is no language in the Controlled Substances Act, Code of Federal Regulations, any other statute or regulation, or any formal notice promulgated by DEA stating that a manufacturer is required to know its customers' customer); 163:25-164:4 ("Q: Do you know if DEA ever informed manufacturers formally that they were required to know their customers' customer? A: Did they ever require it? Not to my knowledge, no."); *See also* Prevoznik Tr. Vol. 1 325:8-12 ("Q: Has the DEA ever provided guidance to the industry in writing informing registrants that they are to know their customers' customers? A: Not that I'm aware of.")

[76] Plaintiff's motion pg. 66.

[77] *See, e.g.*, Knapp Decl. Ex. 57 (ALLERGAN_MDL_03738529) at -8532 (reflecting multiplier of 1.5 for distributors and wholesalers in 2004); *Id.* (reflecting multipliers of 1.25 for wholesalers and distributors, and 1.5 for chains in 2010); Knapp Decl. Ex. 58 (Acquired_Actavis_01675888) (reflecting multipliers of 1.25 for all classes of trade in 2013).

number of monthly SOM investigations rose.[78] But Plaintiffs' own expert testified he had no evidence that the Watson SOM staff performed any less effectively in 2012 than in 2009.[79]

Plaintiffs argue that "[t]he Watson system affirmatively allowed customers to get around [SOM] violations by canceling the order, or cutting the quantity."[80] The record instead makes clear that Watson required its customers to provide legitimate justifications before allowing them to reduce or cancel orders,[81] and in 2011, it reported its customer TopRx for cancelling orders without sufficient justification.[82] Watson's DEA Affairs team investigated TopRx and determined that the orders were suspicious; it then cancelled all other pending orders, discontinued sales of controlled substances to the customer, and reported the customer to the DEA.[83]

With respect to both of Allergan's legacy SOM systems, Plaintiffs make a baseless assertion that the "automated portion" of those systems only flagged orders of unusual size, but not frequency or pattern "in real time."[84] This is incorrect. Among other things, both Watson's and Actavis's algorithms accounted for the number of times a customer ordered each month in order to calculate their average per order, which directly addresses frequency, and Watson's algorithm also specifically looked at patterns within the customer's class of trade.[85] Further, DEA witnesses testified that there was no requirement that size, frequency, or pattern be accounted for within the "automated portion" of any system, or "in real time," as Plaintiffs assert.[86]

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[78] Mot. at 67.
[79] Rafalski Tr. 772:10-774:23.
[80] Mot. at 66.
[81] *See, e.g.*, Knapp Decl. Ex. 59 (ALLERGAN_MDL_04164213) (Watson explaining to customer that "even with a reduction or cancellation we would ask for a reason for the reduction or cancellation"); Knapp Decl. Ex. 60 (ALLERGAN_MDL_04164345) (requiring a reason when a customer asked to cancel an order).
[82] Knapp Decl. Ex. 61 (ALLERGAN_MDL_02187198); Knapp Decl. Ex. 62 (ALLERGAN_MDL_02467197); Napoli Tr. 260:3-261:19; 340:15-21.
[83] *Id.*
[84] Mot. at 63, 68.
[85] Pls. Ex. 485; Knapp Decl. Ex. 63 (ALLERGAN_MDL_02081605).
[86] *See* Prevoznik Tr. 180:12-15; Ashley Tr. 88:11-13.

In a last ditch effort to portray Allergan as violating the CSA, Plaintiffs make a series of half-hearted allegations about both Watson's and Actavis's SOM systems that, even if true, would be immaterial to whether the systems were legally compliant. For example, Plaintiffs assert that Actavis's reports to the DEA were "meaningless" because of the "lack of analysis" of the data they contained; that the Watson multiplier was "set by people instead of an algorithm;" that Watson allowed orders to be shipped based on internal justification; and that neither Watson's nor Actavis's automated system "differentiate[d] among NDC codes for drugs with a higher risk of diversion."[87] But ***none*** of these purported criticism are based on requirements of the CSA or the federal regulations, which set forth ***no*** requirements on which details to include in a report, how to set up an algorithm, appropriate methods to perform due diligence, or whether to "differentiate among NDC codes."[88]

Finally, Plaintiffs cite no authority for their position that Allergan is required to have a SOM program today, despite the undisputed fact that it is not a DEA registrant. This is because the DEA has testified unequivocally that a "non-registrant" has "no duty to maintain effective controls to prevent diversion."[89]

F. Endo and Par Defendants Complied With Their Obligations Under The CSA

Plaintiffs have also failed to meet their burden of establishing "that there is no genuine dispute of material fact" as to Endo, Qualitest, and/or Par.

DEA has long made clear that all relevant factual circumstances must be considered in determining whether a registrant has complied with its SOM obligations under the CSA.[90] There

[87] Mot. at 64, 66, 67, 69.
[88] Ashley Tr. 27:14-19; 88:2-10; 287:3-8; Prevoznik Tr. Vol. 1 212:14-20; 216:4-10; Woods 30(b)(6) Tr. 31:3-12.
[89] Prevoznik Tr. Vol. 2 515:11-516:1 (Dkt. 1969-13/1983-10).
[90] Prevoznik Tr. Vol. 1 166-69, 212-13, 216-17, 271-84, 291-96, 299-308, 446-448; Rannazzisi Tr. 44-46, 114-115; Wright Tr. 194-97.

is no "one-size-fits-all" approach to developing a suspicious order monitoring program.[91] Rather, the only way to determine whether a program is compliant is to undertake an analysis of the particular factual circumstances of the registrant. At a minimum, there are disputed issues of material fact that preclude summary judgment as to Endo, Qualitest, and Par.

1. Genuine Issues of Material Fact Preclude A Finding That Endo Failed To Maintain Effective Controls Against Diversion

Plaintiffs explicitly acknowledge that Endo was *not* technically a registrant because it outsourced the manufacture and distribution of its opioids. Mot. at 44 n.62; *see also* Rafalski Rpt. 173; 21 U.S.C. § 822 (defining who must register by reference to locations where manufacturing or distribution occurs). Because the CSA and its diversion and suspicious order monitoring regulations apply only to DEA *registrants* (*see*, *e.g.*, 21 C.F.R. § 1301.74(b)), Plaintiffs effectively concede that Endo is not subject to those legal obligations. Plaintiffs' argument that Endo did not to comply with its "***CSA*** [d]uties to [m]aintain [e]ffective [c]ontrols [a]gainst [d]iversion" thus fails for this reason alone. Mot. at 43 (emphasis added).[92]

But even if it did have the legal obligations of a registrant under the CSA, the evidence demonstrates that Endo voluntarily operated an appropriate SOM program. Thus, while Plaintiffs assert that Endo did not "maintain effective controls against diversion because it employed a rigid 'excessive' order system operated by sales and customer service personnel" and "failed to conduct any meaningful due diligence of its customers" (Mot. at 45), the record demonstrates otherwise.

[91] Wright Tr. 132-133; Prevoznik Tr. 164-65, 179-81, 212-13, 220-224, 271-84.

[92] Plaintiffs assert that Endo "has conceded that it owed a duty to maintain effective controls against diversion," implying that there has been some concession regarding duties under the CSA. Mot. at 44, n. 62. That is not correct. The documents to which Plaintiffs cite describe generally, for example, the "sophisticated controls and monitoring" at facilities where Endo products are manufactured, and the fact that DEA inspects those facilities, which "have close working relationships with their respective law enforcement agencies." *E.g.*, Pls. Ex. 131 (ENDO-CHI_LIT-00234564) (Risk Minimization Action Plan for Opana ER). These documents cannot create a legal duty under the CSA. The question of an entity's obligations under the CSA is a matter of statutory law.

Endo has long had a SOM program in place.[93] Far from failing to "conduct any meaningful due diligence," Endo has flagged and held all orders of interest for its products classified as controlled substances.[94] Plaintiffs contend that Endo's SOM program is insufficient because it did not report a suspicious order to DEA, but as Stephen Macrides, Endo's 30(b)(6) witness, testified, "any orders that were deemed of interest based on our internal reviews under our suspicious order monitoring system would have been reviewed and investigated" and Endo would not have shipped if it concluded the order was suspicious after a thorough review.[95] And, as noted above, Plaintiffs have not identified a single order from Endo that was improperly shipped.

Importantly, DEA was aware of Endo's program and never communicated that the program was problematic, let alone non-compliant.[96] Thus, for example, in 2003, Endo met with the DEA regarding the launch of its oxycodone product, including discussion of Endo's strategy for risk management and anti-diversion.[97] In 2006, Endo met with the DEA contemporaneously with the launch of Opana ER to discuss the product's introduction to the market and to explain to the DEA the risk management efforts Endo would undertake.[98] This included procedures and efforts to monitor for orders of unusual size, frequency, or pattern.[99] In 2007, Endo incorporated monitoring for excessive orders as part of the Opana ER RiskMAP, which Endo developed in conjunction

[93] Walker Tr. 49 (Dkt. 1971-20/1985-12).
[94] Macrides Tr. 100-101 (Dkt. 1966-11/1981-5); *see also* Morris Decl. Ex. 64 Endo Safeguards to Prevent Opioid Diversion (ENDO-OPIOID_MDL-05967491); Morris Decl. Ex. 65 Presentation "Modified-Release Opioid Risk Management Program: Safety Overview" (ENDO-OPIOID_MDL-05967825).
[95] Macrides Tr. 100-101, 544, 548-49.
[96] As the testimony from the DEA witnesses in this case reflects, this is strong evidence that a program indeed satisfies CSA obligations, because when the DEA encounters material compliance issues with a diversion or SOM program during audits and reviews, DEA procedure is to bring that deficiency to the attention of the entity in question and take appropriate action. Rannazzisi Tr. 114-15, 255-60; Prevoznik Tr. Vol. 1 179-81, 212-13, 216-17, 271-84, 446-48.
[97] Macrides Tr. 121-122; Morris Decl. Ex. 66 Notes From Endo Pharmaceuticals Meeting with DEA (Sept. 30, 2003) (ENDO-OPIOID_MDL-01692323).
[98] Morris Decl. Ex. 67 July 2006 Email re DEA Meeting (ENDO-OPIOID_MDL-00852926).
[99] *Id*.

with the FDA to address risks associated with the product and to establish procedures designed to minimize those risks.[100]

Moreover, as circumstances and technology evolved over time,[101] Endo continued to enhance its SOM program over the years.[102] In April 2010, UPS (a DEA licensed third party vendor for distribution of Endo's controlled substances) began providing additional SOM algorithm services to Endo in addition to Endo's internal program.[103] This added review put to use unique information UPS possessed as the DEA license holder and shipment/delivery provider for multiple companies. Products that were designated for SOM assessment were flagged in the UPS order management system and held until evaluated.[104] Plaintiffs falsely contend that "Endo's apparent justification" for its SOM program was that UPS "had its own SOM program." Mot. at 45. The record reflects, however, that Endo did not exclusively rely on UPS. As Mr. Macrides explained, Endo conducted its own "thorough investigation" of orders of interest and UPS simply provided an "additional check."[105]

On this record, there simply is no basis to find that Endo breached any duty to maintain effective controls against diversion. At a minimum, there are genuine issues of material fact that preclude such a determination on summary judgment.

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[100] Morris Decl. Ex. 68 Endo Risk MAP (June 2007) (ENDO-OPIOID_MDL-00299957).
[101] Wright Tr. 133-34 (noting that SOM programs had to be "adaptive").
[102] Macrides Tr. 346.
[103] *Id.* at 548.
[104] *Id.* at 543-548.
[105] Macrides Tr. 548. Plaintiffs also attempt to frame UPS's program as insufficient as a result of Endo's routine audit in 2013, which identified opportunities for improvement. Mot. at 45. However, such an audit is a normal and appropriate activity for a company to undertake as part of a vendor relationship. Among other things, Endo at that time was looking to review the order receipt process, additional checks/balances for validating orders, order escalation process, and the review of orders of interest from past 12 months. Morris Decl. Ex. 69 (SOMS Process Flow ENDO-OPIOID_MDL-05948042). Certain areas for improvement were identified and subsequently addressed by both UPS and Endo. For example, in 2014, Endo expanded and enhanced its own SOM program, including a more advanced algorithm and additional features for reporting. Macrides Tr. 541, 544-45, 610-11.

2. Genuine Issues of Material Fact Preclude A Finding That Qualitest Failed To Maintain Effective Controls Against Diversion

What Plaintiffs refer to in their brief as "Qualitest" is a separate group of companies that were not affiliated with Endo until November 2010. Plaintiffs contend that Qualitest violated its duties under the CSA because "until at least the spring of 2013, it applied SOM review only to 'retail' customers, used a rigid formula that did not examine orders for unusual size, frequency, or pattern or account for class of trade" and that "[e]ven after Qualitest revamped its SOM program in late 2013, it lacked real rigor, independence, and consistency." Mot. at 47. The record contradicts these contentions. Qualitest had a SOM program in place that was continuously enhanced over time.

Plaintiffs misleadingly focus on the fact that in August 2008 a third-party consultant reviewed Qualitest's SOM program.[106] *See* Mot. at 47. Plaintiffs omit, however, that a month later in September 2008, Qualitest was inspected by the DEA, with a focus on the company's SOM program.[107] The DEA did not initiate any action following that inspection. Rather, following the meeting, Qualitest notified the DEA by letter of Qualitest's updated policy on the distribution of certain controlled substances.[108] This letter highlighted Qualitest's past cooperation with DEA, noting that electronic reports of all controlled substance sales had been submitted to DEA over the past year.[109] DEA took no action against Qualitest.

In the years following, Qualitest continued to enhance its SOM program, working with the DEA and responding to feedback the agency provided. For example, in March 2013, DEA met with representatives of Qualitest, as well as Endo, concerning Qualitest's suspicious order

[106] Macrides Tr. 387.
[107] Morris Decl. Ex. 70 Sept. 2008 Email Chain (PAR_OPIOID_MDL_0000399716).
[108] Morris Decl. Ex. 71 Oct. 30, 2008 Letter (PAR_OPIOID_MDL_0000398657).
[109] *Id.*

monitoring program.[110] Plaintiffs selectively quote from DEA's notes of that meeting to imply that DEA had done a formal investigation and concluded that Qualitest's monitoring activities prior to 2013 were "inadequate." Mot. at 50 (citing Ex. 152). The DEA's notes reflect that the purpose of that meeting was "both educational and informative." *Id.* The goal was to provide information in order for the company to improve, not to make any finding as to whether there had been a violation of the CSA. Indeed, as DEA's notes describe it, the "meeting was to inform, educate, provide pertinent ARCOS data, cover national trends on drug abuse and diversion." *Id.* For its part, Qualitest explained, among other things, that its SOM program was "currently based on historical purchases by individual customer (thresholds)," but that it is "seeking to update the[] computer system and to improve the[] suspicious order monitoring system" *Id.*[111] As was the case in 2008, DEA provided feedback to Qualitest, but did not initiate any investigation, enforcement action, or order to show cause as a result of this meeting.

Responding to this DEA feedback in 2013, Qualitest undertook additional enhancements, above and beyond what the SOM regulation requires.

For example, in May 2013, Qualitest signed a contract with a well-known vendor to license specialized software that included a statistical formula to evaluate all orders for suspicious activity.[112] By June 2013, Qualitest also had engaged Pharma Compliance Group to manage customer visits, and a customer audit program was initiated in November 2013.[113] That same month, Qualitest instituted a SOM development plan that consisted of initial order evaluations for

[110] Macrides Tr. 296-97, 318, 346.
[111] *See also* Macrides Tr. 346 (from the perspective of company, at the 2013 meeting, "DEA was providing us guidance across a number -- number of areas of our SOM system as to how we could improve. In fact from the time that -- from the 2011 time frame onwards, prior to this meeting, we had already identified a number of areas within our overall DEA compliance responsibilities where we could enhance and improve, not just within suspicious order monitoring, but across the full range of DEA compliance").
[112] Morris Decl. Ex. 72 Statement of Work (PAR_OPIOID_MDL_0002016128); *see also* Macrides Tr. 463–65.
[113] Morris Decl. Ex. 73 SOM Improvement Program Notes (PAR_OPIOID_MDL_0000372491).

direct customers, use of chargeback data to review indirect customers in certain circumstances, and customer due diligence visits.[114] Qualitest also met with its internal chargeback data expert to develop reports that could be used to evaluate its customer data.[115] And additional SOM personnel were recruited and hired by Qualitest in the following months.[116]

In August 2013, Qualitest requested a meeting with DEA to update them on several organizational enhancements, site investments to tighten security, quota status updates, SOM progress following the March 6, 2013 meeting, and expansion plans.[117] Notes from this meeting indicate that DEA was impressed with Qualitest's efforts.[118]

Plaintiffs misleadingly contend that Qualitest has been the subject of a variety of DEA investigations. Mot. at 52. However, they have omitted the fact that none of the investigations or enforcement actions directly involved the SOM and reporting issues raised by Plaintiffs. For example, one related to Alprazolam, which is a benzodiazepine, not an opioid medication. *See* Pls. Ex. 168 (PAR_OPIOID_MDL_ 0000399716). Another concerned alleged recordkeeping violations. See Pls. Ex. 164 (PAR_OPIOID_MDL_00010592826). Each investigation related not to Qualitest's SOM program but rather to other DEA regulatory matters and was generally resolved quickly and cooperatively.

Plaintiffs' rhetoric that Qualitest's program was "nothing more than window dressing," Mot. at 51, is devoid of any factual support. The evidence reflects a program that was robust, with review and input by the DEA. Plaintiffs have failed to show that Qualitest violated its duties under

[114] *Id.*; Macrides Tr. 510, 521–24.
[115] Morris Decl. Ex. 73 SOM Improvement Program Notes (PAR_OPIOID_MDL_0000372491).
[116] Macrides Tr. 510.
[117] Morris Decl. Ex. 74 August 2013 Letter (PAR_OPIOID_MDL_0001596543). Subsequently, Qualitest also drafted several SOPs for new account approval and existing account review; customer due diligence visits; cage and vault personnel; and identifying, blocking, and reporting suspicious orders. *See* Morris Decl. Ex. 75 Dec. 2013 SOP (PAR_OPIOID_MDL_0000097389); Morris Decl. Ex. 76 Dec. 2013 SOP II (PAR_OPIOID_MDL_0000097381); Morris Decl. Ex. 77 SOP III (PAR_OPIOID_MDL_0000097379).
[118] Morris Decl. Ex. 78 Meeting Notes (PAR_OPIOID_MDL_0001630566).

the CSA as a matter of law.[119] At a minimum, there are genuine issues of material fact that preclude such a determination on summary judgment.

3. There Are Genuine Issues of Material Fact Precluding A Finding That Par Failed To Maintain Effective Controls Against Diversion

As with Endo and Qualitest, Plaintiffs have failed to meet their burden with respect to Par. Plaintiffs contend that the Par, which became affiliated with Endo in 2015, violated the CSA "because it had no effective, independent SOM program prior to 2015 and, thereafter, operated under the deficient program Qualitest used." Mot. at 52. Such broad assertions ignore key factual context necessary to evaluate Par's SOM program. For instance, the record reflects that prior to 2011, Par did not manufacture any Schedule II controlled substances.[120] In 2011, the company began manufacturing a limited amount of one Schedule II opioid medication (less than 325,000 total pills), and subsequently gradually increased its production of other Schedule II medications over the next few years following 2011. *Id.* During this period, Par had a SOM policy in place.[121] The record thus contradicts the assertion that Par had "no" SOM program prior to 2015.

Moreover, Par continued to enhance its suspicious order monitoring program in subsequent years, particularly after 2015 when it became affiliated with Endo. Par transitioned to the SOM program managed by Qualitest.[122] The Qualitest DEA Compliance team began to manage all SOM

[119] Plaintiffs also try to characterize Qualitest's customer termination policy, in which termination of its largest customers had to be approved by senior management, as an example of how the monitoring program was not applied "consistently." Mot. at 51. This is misleading at best. It is not unusual or unexpected for a company to vest the authority to discontinue large commercial relationships with its executive team, rather than the SOM team. And Plaintiffs make no attempt to support their assertion that this fact somehow constitutes a violation of the CSA.

[120] Plaintiffs argue that "Par was selling generic opioids prior to 2010," Mot. at 52, but this is incorrect. Morris Decl. Ex. 79 Ex. A. to PAR Supp. Objections/Responses to Plaintiffs' Interrogatories No. 33 -- Mar. 4, 2019) (showing no production of Schedule II medications prior to 2011 (Chlorphen/Hydrocodone was classified as a schedule III) and increases in volume for some Schedule II products from 2011 to 2014)

[121] *See, e.g.*, Morris Decl. Ex. 80 2012 SOP (PAR_OPIOID_MDL_0001410508). Par also had previously put a SOM policy in place in April 2012.

[122] Macrides Tr. 248-49.

processes, including running Par controlled substances orders through Qualitest's SOM program.[123]

DEA also was aware of Par's SOM activities. DEA visited Par in 2009[124] and 2012,[125] and did not initiate any enforcement action, or identify any issues with Par's SOM program, following either inspection.

There are disputed issues of material fact from which a reasonable trier of fact could conclude that Par did not violate any duties it had under the CSA. Plaintiffs' motion must be denied as to Par as well.

CONCLUSION

This Court should deny Plaintiffs' Motion for Partial Summary Adjudication that Defendants Did Not Comply with Their Duties Under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them.

Dated: July 31, 2019

Respectfully submitted,

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[123] Morris Decl. Ex. 81 Mar. 2016 Email (PAR_OPIOID_MDL_0001596366).
[124] Morris Decl. Ex. 82 Buzzeo Audit Report (PAR_OPIOID_MDL_0001053153) at -3155 ("The last DEA inspection was in July 2009. It was stated that no issues were discovered by the DEA.").
[125] Morris Decl. Ex. 83 2015 Buzzeo Audit Report (PAR_OPIOID_MDL_0001024034) at -4039 ("The DEA conducted a scheduled regulatory inspection in 2012. . . . No adverse consequences were noted.").

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CERTIFICATE OF SERVICE

I, Brien T. O'Connor, hereby certify that the foregoing document was served via file transfer protocol and email to all counsel of record.

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LOCAL RULE 7.1(f) CERTIFICATION

This brief, which has 56 pages, adheres to the limits set forth in the Court's Order Regarding Pretrial Motions for "Track One" Trial, ECF No. 1653 and subsequent agreement by the parties, approved by Special Master Cohen.

Dated: July 31, 2019

/s/ Brien T. O'Connor
Brien T. O'Connor

APPENDIX A

Deposition Trancripts	Date	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Ashley, Demetra	03/15/19	Third Party	1956-7	1974-7
Baran, Nancy	12/11/18	Defendant	1956-13	1974-13
Buthusiem, Edward	05/10/19	Defendant	1939-5	1936-5
Cardetti, Lisa	01/10/19	Defendant	1959-17	1975-17
Crowley, Jack	01/10/19	Defendant	1961-8	1976-8
Dempsey, Michele	01/22/19	Defendant	1961-12	1976-12
Dempsey, Michele	03/08/19	Defendant	1961-13	1976-13
Gillies, John	02/07/19	Defendant	1962-10	1977-15
Harper, Karen	01/15/19	Defendant	1962-19	1977-24
Keller, Lacey	06/13/19	Plaintiff	1963-13	1979-6
Macrides, Stephen	03/15/19	Defendant	1966-11	1981-5
McCann, Craig	05/09/19	Plaintiff	1966-17	1981-12
McCormick, Jinping	01/09/19	Defendant	1966-19	1981-14
Moskovitz, Bruce	11/14/18	Defendant	1968-11	1982-7
Moskovitz, Bruce	01/09/19	Defendant	1968-10	1982-6
Napoli, Thomas	01/17/19	Defendant	1968-16	1982-12
Neely, Kate	01/08/19	Defendant	1968-17	1982-13
New, Bonnie	02/12/19	Defendant	1968-19	1982-15
Prevoznik, Thomas	04/17/19	Third Party	1969-12	1983-9
Prevoznik, Thomas	04/18/19	Third Party	1969-13	1983-10
Prevoznik, Thomas	05/17/19	Third Party	1969-14	1983-11
Rafalski, James	05/14/19	Plaintiff	1969-19	1983-16
Rannazzisi, Joseph	04/26/19	Third Party	1969-20	1983-17
Ratliff, William	12/19/18	Defendant	1970-1	1983-19
Rausch, James	11/16/18	Defendant	1970-3	1983-21
Seid, Stephen	12/13/18	Defendant	1970-20	1984-13
Spaulding, Eileen	02/05/19	Defendant	1971-1	1984-19
Vorsanger, Gary	01/17/19	Defendant	1971-17	1985-9
Walker, Lisa	12/04/18	Defendant	1971-20	1985-12
Whitelaw, Seth	05/17/19	Plaintiff	1972-7	1985-19
Woods, Mary	01/10/19	Defendant	1972-11	1985-23
Wright, Kyle	02/28/19	Third Party	1972-12	1985-24

Expert Reports	Date	Pltf/Def	Sealed Dkt No.	Public Dkt No.
Buthusiem, Edward	05/10/19	Defendant	1939-5	1936-5
Cohen, Stephen	05/10/19	Defendant	1939-9	1936-9
Colder, Karl	05/31/19	Defendant	1939-10	1936-10
Keller, Lacey	04/15/19	Plaintiff	2000-7	1999-7
McCann, Craig J.	03/25/19	Plaintiff	2000-14	1999-13
McCann, Craig J. (2d Supplemental)	04/15/19	Plaintiff	2000-16	1999-15
Nicholson, Sean	05/10/19	Defendant	1939-27	1936-27
Rafalski, James	04/15/19	Plaintiff	2000-22	1999-21
Whitelaw, Seth	04/15/19	Plaintiff	2000-26	1999-25